The agency must also make these assessments and analyses "available to the public."[487] Executive Order 13563 reaffirms these principles and requirements, explaining that agencies "must take into account benefits and costs, both quantitative and qualitative."[488]

Agencies are further encouraged to weigh the costs and benefits of developing higher information quality in OMB's Information Quality Guidelines.[489] Costs that the Guidelines encourage agencies to consider include "costs attributable to agency processing effort, respondent burden, maintenance of needed privacy, and assurances of suitable confidentiality."[490] EPA's existing information quality guidelines track the OMB Guidelines closely. EPA's disregard of the Guidelines' recommended weighing costs and benefits further contributes to the arbitrariness of EPA's failure to consider the costs of the Proposal.

The Proposal's failure to analyze and disclose costs and benefits cannot be cured in a final regulation. Should EPA not abandon this misguided Proposal, it must re-propose it after first analyzing its costs (both to public health, to researchers, and to the agency itself) and benefits, and providing the requisite opportunity for public comment on its analysis. As discussed further below in Section VIII.D, the public cannot meaningfully comment on the proposed rule without understanding the actual costs and benefits of the Proposal, the alternatives EPA considered, and the analyses underlying EPA's assessments.

VI. EPA Fails to Comply with the Paperwork Reduction Act.

EPA and the White House Office of Management and Budget (OMB) must scrutinize the Proposal for its information collection burden, as that concept is defined under the Paperwork Reduction Act (PRA).[491] The only reference to the PRA in the Proposal is EPA's denial that this action "contain[s] any information collection activities" or "impose[s] an information collection burden."[492] But if finalized, the Proposal would significantly increase that burden in the rulemakings to which it applies. EPA and OMB cannot rationally ignore such an entirely foreseeable impact when considering this Proposal.

The PRA institutes procedural safeguards to "minimize the paperwork burden for individuals, small business, educational and nonprofit institutions," and others.[493] It requires that, prior to initiating a "collection of information," agencies must "provide 60-day notice in the Federal Register . . . to solicit comment to," inter alia, "evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency," "evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information,"

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[487] Exec. Order 12,866 § 6(a)(3)(E)(i).
[488] Exec. Order 13563 § 1(a) (Jan. 18, 2011).
[489] OMB, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Republication*, 67 Fed. Reg. 8452, 8453 (Feb. 22, 2002).
[490] OMB, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Republication*, 67 Fed. Reg. 8452, 8453 (Feb. 22, 2002).
[491] *See* 44 U.S.C. § 3502(2), (3) (defining "burden" and "collection of information").
[492] *See* 83 Fed. Reg. at 18,772.
[493] 44 U.S.C. § 3501(1).

and "minimize the burden of the collection of the information on those who are to respond."[494] After evaluating public comments, agencies must submit the proposed collection of information to OMB for additional review and publish a notice in the Federal Register setting forth "an estimate of the burden that shall result from the collection of information" and "notice that comments may be submitted to the agency and [OMB]."[495] Any such collection of information is subject to OMB approval.[496] OMB is required to determine "whether the collection of information . . . is necessary for the proper performance of the functions of the agency."[497] A negative determination precludes the agency from initiating the collection of information.[498]

The requirements that EPA would impose through this Proposal qualify as collections of information under the PRA. The statute defines "collection of information" to include "the obtaining [or] causing to be obtained . . . of facts or opinions by or for an agency, regardless of form or format, calling for . . . answers to identical questions posed to, or identical reporting or recordkeeping requirements imposed on, ten or more persons . . . ."[499] OMB regulations emphasize the breadth of this definition, specifying that "[a] Collection of information may be in any form or format, including . . . reporting or recordkeeping requirements; . . . policy statements; . . . rules or regulations; . . . oral communications;" and others.[500] "Any recordkeeping, reporting, or disclosure requirement contained in a rule of general applicability is deemed to involve ten or more persons."[501] The definition of "collection of information" is agnostic as to whether disclosure is "mandatory, voluntary, or required to obtain or retain a benefit," and to whether disclosure is to an agency or "members of the public or the public at large."[502]

The Proposal would impose a burden that falls squarely within the definition of "collection of information." In order to use scientific research, the agency would "obtain[] or caus[e] to be obtained . . . facts." Assuming the requirements are applied consistently, the "questions posed," or "reporting or recordkeeping requirements imposed," would be "identical." As the requirements are "contained in a rule of general applicability"—i.e., the instant Proposal—they are "deemed to involve ten or more persons." It makes no difference whether the agency seeks the information through a questionnaire, telephone call, or some other format. Nor does it matter whether the agency directly mandates that entities provide the information, or provides that entities must "voluntary[ily]" provide the information in order for research to be eligible for consideration in important rulemakings.

While EPA has refrained from detailing the mechanics by which entities would provide the information, the agency expressly contemplates that the burden of providing such information would fall at least partly to members of the public whom the PRA exists to

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[494] 44 U.S.C. § 3506(c)(2)(i), (ii), (iv).
[495] *Id.* § 3507(a)(1)(D)(ii)(V), (VI).
[496] *See id.* § 3507(a)(2).
[497] *Id.* § 3508.
[498] *Id.*
[499] 44 U.S.C. § 3502(3)(A)(i).
[500] 5 C.F.R. § 1320.3(c)(1).
[501] *Id.* § 1320.3(c)(4)(i).
[502] *Id.* § 1320.3(c), (c)(2).

protect.[503] For example, proposed regulation 40 C.F.R. § 30.5 provides that, "[w]here data is controlled by third parties, EPA shall work with those parties to endeavor to make the data available in a manner that complies with this section." Moreover, the agency specifically "solicits comment on how to incorporate stronger data and model access requirements in the terms and conditions of cooperative agreements and grants."[504] As noted above, the PRA is implicated when collection of information is "required to obtain or retain a benefit,"[505] and OMB guidance has identified grants as a "Federal benefit" for purposes of the PRA.[506]

EPA cannot evade the PRA requirements by narrowly asserting that "this action" imposes no information collection burden and ignoring the action's entirely foreseeable future impacts. The proposal expressly "is intended to apply prospectively," suggesting that it "prospectively" requires burdensome collections of information in future rulemakings. EPA must not ignore the PRA in this rulemaking, only to claim in future rulemakings that this rule moots or constrains the PRA's application by compelling certain collections of information.

In the alternative, if EPA genuinely believes that this Proposal would not burden the public with new collections of information, then EPA's stated basis for this rulemaking is exposed as a farce. EPA claims that the Proposal would "ensure" that certain data "are publicly available" and expresses specific concern for science "developed outside the agency."[507] Collection of information, including from researchers employed outside of the federal government, is central to the purpose—and essential to the implementation—of the Proposal. Providing this information would inevitably impose a burden on researchers. If the agency does not actually intend to collect information under this Proposal, it underscores that EPA's true purpose is not to increase transparency, but rather to thwart the development and maintenance of vital public health protections on the grounds that the agency lacks the information it would need to support them.

At a minimum, EPA must acknowledge and describe the information collection burden that this Proposal would impose so that OMB and the public can conduct a proper evaluation and provide responsive comments.

VII. The Circumstances Surrounding the Proposed Rule Indicate that it Was Based on a Desire to Suppress Vital Public Health Science for the Benefit of Certain Regulated Industries.

The circumstances surrounding the development of this proposed rule underscore that it is not intended to "strengthen the transparency of EPA regulatory science."[508] Far from furthering EPA's mission of protecting human health and the environment based on the best available science, the Proposal is EPA's effort to implement failed congressional legislation that

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[503] *Cf. id.* § 1320.3(k) (defining "person" for purposes of the PRA).
[504] 83 Fed. Reg. at 18,771.
[505] 5 C.F.R. § 1320.3(c).
[506] *See* Memorandum from Cass R. Sunstein, Administrator, Office of Information and Regulatory Affairs, re: Information Collection Under the Paperwork Reduction Act 3 (Apr. 7, 2010), *available at* www.whitehouse.gov/sites/whitehouse.gov/files/omb/assets/inforeg/PRAPrimer_04072010.pdf.
[507] 83 Fed. Reg. at 18,768, 18770.
[508] 83 Fed. Reg. 18,768.

was intended to suppress rigorous science for the benefit of private industry and at the expense of public health.

EPA's Proposal is largely based upon the HONEST Act of 2017, an unenacted House bill that aimed at undermining climate and regulatory science. Available information about the Proposal's evolution indicates that regulated industries had a disproportionate role in its development. In addition, the Proposal mirrors advocacy tactics employed by the tobacco industry in the 1990's in order to suppress scientific research demonstrating the adverse health effects of cigarettes and second-hand smoke. Finally, the Proposal follows a host of instances in which the Agency, under former EPA Administrator Scott Pruitt, suppressed science and transparency—underscoring the bad faith nature of the purported justifications for this rule.

A. The Proposed Rule is an Attempt by EPA to Implement an Unenacted Congressional Bill, The HONEST Act.

EPA's Proposal is an outgrowth of a failed congressional bill, the HONEST Act. The bill was vigorously supported by Congress members with strong ties to the precise industries that would have benefited from its enactment. Internal and external EPA communications illustrate that the HONEST Act served as a precursor to EPA's Proposal. The intertwined history of the HONEST Act and EPA's Proposal cast doubt on the Agency's proffered rationale.

The HONEST Act

The HONEST Act[509] is a House bill introduced in 2017 by sponsor Representative Lamar Smith (R-TX), and is the latest manifestation of various bills aimed at undermining EPA regulation through limitations on the types of scientific research the Agency may use.[510] The HONEST Act and these related bills were introduced and passed in the House three times, but each time, failed to progress in the Senate.[511]

Like the current Proposal, the HONEST Act was touted by its proponents as an effort to enhance the transparency and credibility of regulatory science at EPA. But the HONEST Act—like the Proposal—would in fact have had the effect of limiting the scope and quality of science underlying EPA actions. Indeed the HONEST Act was widely criticized and opposed by scientists, scientific organizations, medical organizations and other scientific authorities for precisely this reason. For example, eight public health and medical associations including the American Lung Association, American Public Health Association, National Medical Association, and Physicians for Social Responsibility issued an open letter to Congress in spring 2017 opposing the HONEST Act because it "would limit the kinds of scientific data EPA can use

[509] HONEST Act, H.R. 1430, 115th Cong. (2017).
[510] *See* Secret Science Reform Act of 2014, H.R. 4012, 113th Cong. (2014); Secret Science Reform Act of 2015, H.R. 1030, 114th Cong. (2015); H.R. 1430; HONEST Act, S. 1794, 115th Cong. (2017).
[511] On March 2017, Representative Smith introduced the HONEST Act in the 115th Congress. On March 29, 2017, the bill passed the House without amendment. Most recently, Senator Mike Rounds (R-SD) introduced a Senate version of the HONEST Act on September 12, 2017. As with past versions of the bill, the Senate referred the Bill to the Committee on Environment and Public Works, but took no further action.

as it develops policy to protect the American public from environmental exposures and permit violation of patient confidentiality."[512] The American Association for the Advancement of Science and twenty-two other leading scientific organizations and research universities likewise sent a letter to House Majority Whip Kevin McCarthy in March 2017 opposing the bill and warning that it could lead to a "situation where the EPA would be prevented from using the best available science and disseminating public information in a timely fashion."[513] As we have noted elsewhere in these comments, the Congressional Budget Office – after consulting with EPA staff – likewise concluded that the HONEST Act would "significantly reduce the number of studies that the agency relies on when issuing or proposing covered actions."[514]

That the HONEST Act would suppress rather than promote good science at EPA is not surprising, given that the sponsors of the HONEST Act have a history of rejecting established climate science and strong ties to industries that would benefit from limiting the role of science in EPA rulemakings. Representative Lamar Smith is widely known as an opponent of mainstream climate science and public health and environmental safeguards.[515] In a July 24, 2017 opinion piece, Representative Smith lauded the benefits of increased atmospheric carbon dioxide: "A higher concentration of carbon dioxide in our atmosphere would aid photosynthesis, which in turn contributes to increased plant growth."[516] Smith and the sponsor of the Senate version, Mike Rounds, also receive substantial contributions from the same industries that will benefit from the proposal.[517]

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[512] Letter from Alliance of Nurses for Health Environments, American Lung Association, American Public Health Association, American Thoracic Society, Asthma and Allergy Foundation of America, Health Care Without Harm, National Medical Association, and Physicians for Social Responsibility to U.S. House (Mar. 27, 2017), http://www.lung.org/assets/documents/advocacy-archive/letter-to-us-house-opposing-2.pdf.

[513] Letter from American Association for the Advancement of Science et al. to Rep. Kevin McCarthy (Mar. 28, 2017), https://mcmprodaaas.s3.amazonaws.com/s3fs-public/HR%201430%20HONEST%20Act%20Multisociety%20Letter%20of%20Concern.pdf.

[514] CBO, H.R. 1430, Honest and Open New EPA Science Treatment (HONEST) Act of 2017 at 2 (Mar. 29, 2017), *https://www.cbo.gov/system/files?file=115th-congress-2017-2018/costestimate/hr1430.pdf.*

[515] *See, e.g.*, Rep. Lamar Smith, *Climate Change: Seven Indisputable Facts*, The Hill (Sept. 8, 2017, 5:46 PM), http://thehill.com/opinion/op-ed/252989-climate-change-seven-indisputable-facts ("Like all climate alarmists, the president wants Americans to believe there is no uncertainty about climate change….But the truth is there are more questions about climate change than there are answers. For instance, even the most advanced climate models all failed to predict the lack of warming the Earth has experienced over the last 18 years."); Lamar Smith, *The Climate Change Religion*, The Wall Street Journal: Opinion | Commentary (Apr. 23, 2015, 7:35 PM), https://www.wsj.com/articles/the-climate-change-religion-1429832149, ("When assessing climate change, we should focus on good science, not politically correct science."); Lamar Smith, *Smith: EPA Hides Truth about Climate Regulations*, Media Center: Press Releases (Aug. 13, 2014), https://lamarsmith.house.gov/media-center/press-releases/smith-epa-hides-truth-about-climate-regulations.

[516] Lamar Smith, *Don't Believe the Hysteria over Carbon*, The Daily Signal Energy: Commentary (July 24, 2017), https://www.dailysignal.com/2017/07/24/dont-believe-hysteria-carbon-dioxide/

[517] Throughout his congressional career, Representative Smith received over $787,047 in contributions from the oil and gas sector. Center for Responsive Politics, *Rep. Lamar Smith – Texas District 21: Summary*, Open Secrets: Congress, https://www.opensecrets.org/members-of-congress/summary?cid=N00001811&cycle=CAREER&type=I (last visited June 6, 2018). From 2011 to 2018, Senator Rounds received over $215,000 from oil and gas companies alone. Center for Responsive Politics, *Sen. Mike Rounds – South Dakota: Summary*, Open Secrets: Congress, https://www.opensecrets.org/members-of-congress/summary?cid=N00035187&cycle=CAREER&type=I (last visited June 14, 2018).

Representative Smith also has ties to EPA staff who drafted the proposal, underscoring the close connection between his failed legislation and this proposed rule. Dr. Richard Yamada, former professional staff member on Smith's House Committee on Science, Space & Technology now serves as the Deputy Assistant Administrator for EPA's Office of Research and Development.[518] At EPA, Dr. Yamada has participated in the drafting and development of the Agency's version of the proposal.[519]

The HONEST Act as Predecessor for the Proposal

As this section details, it is clear that the HONEST Act is a direct predecessor of this proposed rule and that both initiatives share the same purpose: to undermine EPA's use of rigorous science in crafting health and environmental protections. The language used in the proposal shares strong similarities with the HONEST Act. Furthermore, internal and external communications from EPA leadership demonstrate the proposal's origins in the HONEST Act.

While lengthier than the congressional HONEST Act, EPA's proposal contains parallel language to the bill. One can compare examples from the text of the 2017 HONEST Act as passed in the House, to the text of the proposal from the Final Federal Register Notice:

> *The HONEST Act of 2017*
> An Act: To prohibit the [EPA] from proposing, finalizing, or disseminating regulations or assessments based upon science that is not transparent or reproducible.....
>
> The Administrator shall not proposed, finalize, or disseminate a covered action unless all scientific and technical information relied on to support such covered action is—(A) the best available science; (B) specifically identified; and (C) publicly available online in a manner that is sufficient for independent analysis and substantial reproduction of search results....[520]
>
> *Strengthening Transparency in Regulatory Science Proposal*
> EPA shall clearly identify all studies (or other regulatory science) relied upon when it takes any final action. EPA should make all studies available to the public to the extent practicable . . . When promulgating significant regulatory actions, the Agency shall ensure that dose response data and models underlying pivotal regulatory science are publicly available in a manner sufficient for independent validation.[521]

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[518] EPA, *Dr. Richard Yamada*, EPA Research, https://www.epa.gov/research/dr-richard-yamada. (last updated Jan. 12, 2018).

[519] Email from Richard Yamada, Deptuy Assistant Adm'r, Office of Researh and Dev., to Drew Feeley, Policy Counsel, Office of Policy; Brittany Bolen, Acting Assoc. Adm'r, Office of Policy; Clint Woods, Deputy Assistant Adm'r, Office of Air and Radiation; Justin Schwab, Deputy Gen. Counsel, Office of Gen. Counsel; Erik Baptist, Senior Deputy Gen. Counsel, Office of Gen. Counsel; and Nancy Beck, Deputy Assistant Adm'r, Office of Chem. Safety and Pollution Prevention (Jan. 29, 2019, 10:58 PM), https://drive.google.com/file/d/1peMXjBhq6lUYGGNBWbSjpOu1Zh-qLl4p/.

[520] H.R.1430 § 2(b)(1).

[521] Strengthening Transparency in Regulatory Science, 83 Fed. Reg. 18,768, 18,773 (Apr. 30, 2018) (proposed 40 C.F.R. §§ 30.4, 30.5).

The best available science must serve as the foundation of EPA's regulatory actions.[522]

Responsive records released to the Union of Concerned Scientists ("UCS") make evident that the HONEST Act served a predecessor to the proposal. Administrator Pruitt's schedule reveals that he met with Representative Smith on January 9, 2018, less than four months before the Federal Register announcement of the proposal.[523] Emails from Pruitt and his staff, dated just over a week after that meeting, indicate that Smith was working on a "pitch that EPA internally implement the HONEST Act."[524] Subsequent emails sent between Pruitt's EPA staff in February 2018 demonstrate that EPA officials promptly began drafting the proposal.[525]

Before Smith's internal EPA 'pitch,' Agency leadership commented favorably on the HONEST Act of 2017. Although EPA initially estimated that implementation of the act would cost over $250 million per year,[526] that estimate was never reported to the Congressional Budget Office ("CBO"). As CBO's cost estimate determination indicates, EPA political leadership diverged from the earlier estimate and instead assured CBO that the bill could be implemented "with minimal funding."[527] Several news sources have reported that the Administrator's Office of the EPA became involved in communications with CBO, and decided to respond to CBO directly with the assurance the bill could be implemented at 'no cost.'[528]

Finally, in an exclusive interview with the Daily Caller shortly before the proposal's publication, former Administrator Pruitt promised:

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[522] *Id.* at 18,769.

[523] EPA, *Calendar for Scott Pruitt, Administrator*, Senior Leaders Calendars, https://archive.epa.gov/epa/senior-leaders-calendars/calendar-scott-pruitt-former-administrator.html (last visited Aug. 3, 2018) (search starting point field for "Smith," then see entry for Jan. 9, 2018).

[524] Email from Aaron Ringel, Deputy Assoc. Adm'r, Office of Intergovernmental Affairs, to Troy Lyons, Assoc. Adm'r, Office of Congressional and Intergovernmental Relations; David Fotouhi, Deputy Gen. Counsel, Office of Gen. Counsel; Mandy Gunasekara, Principal Deputy Assistant Adm'r, Office of Air and Radiation; and Richard Yamada, Deputy Assistant Adm'r, Office of Research and Dev. (Jan. 16, 2018, 2:28 PM)(on file with Union of Concerned Scientists), https://drive.google.com/file/d/15Z6RKok51uqwkgAmhK3rseTOEJhFo8Sj/.

[525] *See, e.g.*, Email from Richard Yamada, Deputy Assistant Adm'r, Office of Research and Dev., to Nancy Beck, Deputy Assistant Adm'r, Office of Chem. Safety and Pollution Prevention (Jan. 29, 2018, 6:07 PM)(on file with Union of Concerned Scientists), https://drive.google.com/file/d/1DvwXyjzZlPstQx3tVL-jW_Yjv-S7VD2H/; Email from Richard Yamada, Deputy Assistant Adm'r, Office of Research and Dev., to Drew Feeley, Policy Counsel, Office of Policy; Brittany Bolen, Acting Assoc. Adm'r, Office of Policy; Clint Woods, Deputy Assistant Adm'r, Office of Air and Radiation; Justin Schwab, Deputy Gen. Counsel, Office of Gen. Counsel; Erik Baptist, Senior Deputy Gen. Counsel, Office of Gen. Counsel; and Nancy Beck, Deputy Assistant Adm'r, Office of Chem. Safety and Pollution Prevention (Jan. 29, 2019, 10:58 PM), https://drive.google.com/file/d/1peMXjBhq6lUYGGNBWbSjpOu1Zh-qLl4p/.

[526] EPA, Comments on CBO Questions for EPA regarding H.R. xxxx, the HONEST Act of 2017 (n.d.) (on file with Bloomberg Bureau of National Affairs), http://src.bna.com/nAj.

[527] CBO, Cost Estimate: H.R. 1430, Honest and Open New EPA Science Treatment (HONEST) Act of 2017 1 (2017), https://www.cbo.gov/system/files/115th-congress-2017-2018/costestimate/hr1430.pdf.

[528] *E.g.*, Scott Tong, *Critics Say HONEST Act undercuts EPA's use of science*, Marketplace: Sustainability (Apr. 10, 2017, 1:08 PM), https://www.marketplace.org/2017/04/10/sustainability/honest-act-seen-critics-undercutting-epa-s-use-science.

> If we use a third party to engage in scientific review or inquiry, and that's the basis of rulemaking, you and every American citizen across the country deserve to know what's the data, what's the methodology that was used to reach that conclusion that was the underpinning of what — rules that were adopted by this agency.[529]

The Daily Caller directly linked the proposal to the HONEST Act, "Pruitt's pending science transparency policy mirrors Smith's HONEST Act, which passed the House in March 2017."[530]

Spokeswoman for Chairman Smith's House Committee on Science, Space, and Technology, Thea McDonald, also told the Daily Caller: "[t]he chairman has long worked toward a more open and transparent rule-making process at EPA, and he looks forward to any announcement from Administrator Pruitt that would achieve that goal."[531]

1. Available information on the development of the proposal illustrate its industry origins.

The history of the proposal's internal development indicates that certain representatives of regulated industries had a nearly exclusive role in its promulgation, and that industry concerns were given special solicitude by EPA's senior political leadership. Meanwhile, the scientific community and the EPA's own Science Advisory Board were neither involved in the evolution of the proposal nor notified of its initiation until after its official publication in the Federal Register, further suggesting that this proposal is not grounded in a genuine concern for advancing science at EPA and is, in fact, at odds with EPA's mission of protecting human health and the environment.

Nancy Beck, key decision maker and EPA's current Deputy Assistant Administrator of the Office of Chemical Safety and Pollution Prevention, previously served as the Senior Director, Regulatory & Technical Affairs for the American Chemistry Council.[532] While employed by the ACC, Beck submitted a written statement in general support of the HONEST Act.[533]

In internal EPA emails released pursuant to Union of Concerned Scientists' Freedom of Information Act ("FOIA") request, Beck expressed concerns that repeated those of industry. Her concerns that certain language in the proposal might compromise industry confidential business information ("CBI") or alter individual party adjudications were met with assurances by Deputy Assistant Administrator for the Office of Research and Development, Richard Yamada, that the

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[529] Michael Bastach, *Exclusive: Scott Pruitt Will End EPA's Use of 'Secret Science' to Justify Regulations*, The Daily Caller (Mar. 20, 2018, 1:06 AM), http://dailycaller.com/2018/03/19/epa-scott-pruitt-secret-science/.
[530] *Id.*
[531] *Id.*
[532] Nancy Beck, LinkedIn, https://www.linkedin.com/in/nancybbeck/ (last visited June 6, 2018).
[533] *Written Statement of Nancy B. Beck Before the U.S. Senate Committee on Homeland Security and Governmental Affairs, Subcommittee on Regulatory Affairs and Federal Management Regarding a Hearing on the Agency Use of Science in the Rulemaking Process: Proposals for Improving Transparency and Accountability,* American Chemistry Council 1 (Mar. 9, 2017), https://www.hsgac.senate.gov/imo/media/doc/BECK%20TESTIMONY.pdf.

agency would "thread" the proposal "real tight."[534] Concerns about protecting CBI, expressed in Beck's emails, echo her statement in support of the HONEST Act to the House Subcommittee on Regulatory Affairs and Federal Management while she was employed by the ACC.[535]

The proposal's justifications regarding the private-sector burden of regulatory costs reiterates concerns and suggestions about EPA's policy for evaluating science that the Agency received from industry itself. In emails to EPA leadership from May 2014, the National Association of Manufacturers ("NAM") specifically identified dozens of EPA regulations that were "affecting its members," many of which were chemical, air, and water regulations which were based upon the types of research and studies that would be excluded under EPA's proposed rule.[536]

In response to EPA's 2017 proposed rule, Procedures for Prioritization of Chemicals for Risk Evaluations, NAM made recommendations that EPA ensure that TSCA prioritization relied upon "the best available science" in a process that requires "a heightened level of transparency."[537] NAM also provided the EPA with materials that called for reform of EPA's "process for evaluating science to improve transparency and better involve the public."[538] This parallels NAM's 2014 letter to the House in support of that year's version of Rep. Smith's HONEST Act.[539]

The American Petroleum Institute's ("API") Senior Director of Regulatory and Scientific Affairs wrote to the EPA: "[t]he science and data used to support a regulation should be reviewed to determine if they are still valid based on scientific integrity, consistent with EPA's Principles of Scientific Integrity and Policy (2012), with meaningful disclosure of all potential areas of bias, guarding against manipulation or misinterpretation."[540]

API also issued a press release on that same day, May 15, 2017, in which the organization summarized its conversations with EPA: "API today urged the EPA to adopt a

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[534] Email from Richard Yamada, Deputy Assistant Adm'r, Office of Research and Dev., to Nancy Beck, Deputy Assistant Adm'r, Office of Chem. Safety and Pollution Prevention; Erik Baptist, Senior Deputy Gen. Counsel, Office of Gen. Counsel; and Justin Schwab, Deputy Gen. Counsel, Office of Gen. Counsel (Jan. 31, 2018, 7:54 PM)(on file with Union of Concerned Scientists), https://drive.google.com/file/d/1VIUUz2wDTT7c7oxBAU3gSP8lMfipieO5/.

[535] American Chemistry Council, *supra* note 34, at 7.

[536] Letter from the Nat'l Ass'n of Mfs. to Regulatory Reform Officer and Associate Administrator, Samantha K. Dravis (May 15, 2017) *in* Maxine Joselow, *Emails: EPA all ears as industry pitched 'secret science'*, E&E News: Regulations (May 18, 2018), https://www.eenews.net/greenwire/2018/05/17/stories/1060081997, at 169-88.

[537] *Id.* at 184.

[538] *EPA Meeting Briefing Paper*, Nat'l Ass'n of Mfs. (n.d.), *in* Joselow, at 772-6.

[539] Letter from the Nat'l Ass'n of Mfs. to U.S. House of Representatives (Nov. 19, 2014) *in* Nat'l Ass'n of Mfs., *Key Manufacturing Votes: 113th Congress*, Advocacy: Congressional Voting Record, http://www.nam.org/Advocacy/Key-Manufacturing-Votes/113th-Congress/House/HR-4012--the-Secret-Science-Reform-Act-of-2014-sponsored-by-Representative-Dave-Schweikert-(R-AZ)/?__taxonomyid=211. (last visited June 6, 2018).

[540] Letter from the Am. Petroleum Inst. to Regulatory Reform Officer and Associate Administrator, Samantha K. Dravis (May 15, 2017) *in* Joselow, at 1140.

regulatory system that enhances safety and protects the environment while prioritizing the production and refining of American natural gas and oil."[541]

In contrast, EPA's Science Advisory Board ("SAB") leadership was not notified of the rulemaking activity until it was published in the Federal Register, in contravention of Agency practices for communicating major actions such as the proposed rule.[542] EPA also failed to provide the SAB with a description of the proposal.[543]

Despite the SAB's Congressionally-mandated role to formally review and comment on EPA actions of this nature,[544] the SAB and scientific community were not consulted in the development of the rule.[545] Indeed, SAB leadership questioned the scientific support behind the proposal: "[a]lthough the proposed rule cites several valuable publications that support enhanced transparency, the precise design of the rule appears to have been developed without a public process for soliciting input from the scientific community."[546]

SAB leadership took note of the HONEST Act's connection to the proposal, stating the rule was "highly controversial" as indicated by the fact that "a similar legislative effort in the House has been stalled in Congress for several years."[547]

B. EPA's Proposed Rule Mirrors Policies That the Tobacco Industry Advocated for in the 1990's to Suppress Unfavorable Science.

Both this proposed rule and the HONEST Act bear close similarities to policies promoted by the tobacco industry in the 1990's to suppress unfavorable science—further confirming that the proposed rule would degrade the quality of science at EPA and undermine public health. Before EPA's proposed rule and the HONEST Act, Philip Morris (today, Altria) and public-relations firm APCO partnered to establish The Advancement of Sound Science Coalition ("TASSC") in order to "inform the market of the problem with unsound science" that demonstrated adverse health effects of tobacco and second-hand smoke.[548] TASSC led a worldwide publicity campaign in the 1990s to promote "Good Epidemiological Practices" that

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[541] Reid Porter, *API: Regulatory System Should Promote Technological Innovations and Industry Best Practices*, Am. Petroleum Inst.: News (May 15, 2017), http://www.api.org/news-policy-and-issues/news/2017/05/15/regulatory-system-should-promote-technol. (last visited June 6, 2018).

[542] Memorandum from Chair of the SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science, Alison Cullen, to Members of the Chartered SAB and SAB Liaisons (May 12, 2018), https://yosemite.epa.gov/sab/sabproduct.nsf//E21FFAE956B548258525828C00808BB7/$File/WkGrp_memo_2080-AA14_final_05132018.pdf.

[543] *Id.*

[544] Environmental Research, Development, and Demonstration Authorization Act of 1978, 42 U.S.C. § 4365 (1978).

[545] Memorandum from Chair of the SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science, Alison Cullen, to Members of the Chartered SAB and SAB Liaisons (May 12, 2018), https://yosemite.epa.gov/sab/sabproduct.nsf//E21FFAE956B548258525828C00808BB7/$File/WkGrp_memo_2080-AA14_final_05132018.pdf.

[546] *Id.*

[547] *Id.*

[548] *See* APCO Assocs., Revised Plan for the Public Launching of TASSC (Through 1993) (Oct. 15, 1993) (internal document) (on file with UCSF, available online through Truth Tobacco Industry Documents portal).

aimed at undermining U.S. and international regulatory efforts based on epidemiologic studies of passive smoking and lung cancer.[549]

During the same period, Philip Morris made it a strategic priority to pursue legislation and policies to require public disclosure of epidemiological data. A May 1997 planning document advocated for using "existing political and business coalitions" that opposed clean air regulations to promote "legislative solutions to ensure that public policy is based on sound science" and "require epidemiological studies to meet a minimum set of criteria and/or require researchers to make public the underlying data before these studies can be used as a basis for regulations at the state or federal level."[550] In 1998, Powell Tate – a lobbying firm that represented R.J. Reynolds – organized a "secret science" working group focused on "requiring the disclosure of taxpayer-funded analytical data upon which federal and state rules and regulations are based, as well as the analytic data underlying health and safety studies funded by the government . . . ."[551]

Although TASSC no longer exists, its executive director, Steve Milloy, continues the organization's "sound science" rhetoric against other types of regulation through his website, JunkScience.com.[552] In fact, Milloy has personally taken credit for EPA's proposal and was one of a select few invited to Pruitt's public announcement of the proposal earlier this year.[553] After the proposed rule was announced, Milloy told reporters, "I look at this as one of my proudest achievements. The reason this is anywhere is because of Steve Milloy."[554]

C. EPA, Under the Trump Administration, Has a History Of Suppressing Science and Transparency, Undermining the Purported Justifications for the Proposal.

A FOIA request submitted by E&E News uncovered a document emailed by former EPA official David Schnare laying out a strategy to overturn the 2009 Greenhouse Gas Endangerment Finding.[555] In the document, one of the steps contemplated as part of the reconsideration included EPA only relying "on information, data and studies where the original data upon which assessment is based is available to the public. . . . EPA would not rely on any study whose authors refuse to

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[549] Elisa K. Ong and Stanton A. Glantz, *Constructing "Sound Science" and "Good Epidemiology": Tobacco, Lawyers, and Public Relations Firms*, 91 Am. J. of Public Health 1749, 1753 (2001).
[550] Annamaria Baba et al., *Legislating "Sound Science": the Role of the Tobacco Industry,* 95 Am. J. of Public Health S20, S22 (2005).
[551] Memorandum from Leslie Gianelli, Powell Tate, to "Secret Science" Work Group (Apr. 10, 1998), available at https://www.industrydocumentslibrary.ucsf.edu/tobacco/docs/#id=klyc0069.
[552] Emily Atkin, *The EPA is Acting Like Big Tobacco,* The New Republic (Apr. 26, 2018), available at https://newrepublic.com/article/148126/epa-acting-like-big-tobacco.
[553] Robin Bravender, *Pruitt to unveil 'secret science' effort today—sources*, E&E News: EPA (Apr. 24, 2018), https://www.eenews.net/stories/1060079891.
[554] Robin Bravender, *Trump team wanted to kill agency authority on CO2—emails*, E&E News (June 1, 2018), https://www.eenews.net/stories/1060083175.
[555] Document entitled GHG Endangerment Finding Redux, https://www.eenews.net/assets/2018/06/01/document_cw_13.pdf.

provide the underlying data, including computer code used to evaluate and analyze the data."[556] This is just one example among numerous others that this proceeding is not intended to increase transparency, but rather aimed at weakening EPA standards that the current Administration disapproves of, despite their grounding in robust scientific evidence.

EPA's non-transparent approach to this rulemaking, as well as other Agency actions, underscore that the proposal was not offered in good faith. The Agency has removed thousands of webpages from its website, limited public and press access to Agency events, and withheld key data underlying rulemakings and proceedings. These practices cast doubt on EPA's proffered justifications of transparency and accountability.

In EPA's stay of the Oil and Natural Gas Sector: Emissions Standards for New, Reconstructed, and Modified Sources, EPA failed to disclose directly relevant evidence for the basis of revision of the standards consisting of industry compliance reports.[557] Despite the fact that these compliance reports were in the agency's possession and comprised of public documents containing factual data that should have been available for public inspection, EPA has to date still not released all of the compliance reports in its possession.

In August 2017, EDF received information pursuant a FOIA request revealing that more than 1,900 climate-related webpages and files on EPA's website were removed or modified.[558] Many of the removed and modified pages were related to climate change science and impacts, such as "Climate Impact on Health Through Life Stages," "Climate Change Science," and "Methane and Black Carbon Impacts on the Arctic: Communicating the Science."[559]

In January 2018, EDF received additional responsive records to another FOIA request demonstrating that former Administrator Pruitt directed the removal of many climate change science, impacts, and resources pages as well as all material related to the Clean Power Plan on EPA.gov.[560]

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[556] Document entitled GHG Endangerment Finding Redux, https://www.eenews.net/assets/2018/06/01/document_cw_13.pdf.

[557] Comments of Clean Air Council, Clean Air Task Force, Center for Biological Diversity, Earthjustice, Earthworks, Environmental Defense Fund, Environmental Integrity Project, Environmental Law and Policy Center, Natural Resources Defense Council, Sierra Club, and National Parks Conservation Association on Oil and Natural Gas Sector: Emission Standards for New, Reconstructed, and Modified Sources: Stay of Certain Requirements and Oil and Natural Gas Sector Emission Standards for New, Reconstructed, and Modified Sources: Three Month Stay of Certain Requirements Docket No. EPA-HQ-OAR-2010-0505 and Docket No. EPA-HQ-OAR-2017-0346 (Dec. 8, 2017).

[558] *Environmental Defense Fund Obtains Information on Over 1,900 Climate-Related Items Removed from or Modified on EPA Website*, EDF: Press release archive (Aug. 11, 2017), https://www.edf.org/media/environmental-defense-fund-obtains-information-over-1900-climate-related-items-removed-or.

[559] *Id.*

[560] E-mail from Lincoln Ferguson, Senior Advisor, Office of Public Affairs, to Amy Graham, Advisor, Office of Public Affairs; John Konkus, Deputy Associate Administrator, Office of Public Affairs; JP Freier, Associate Administrator, Office of Public Affairs; Liz Bowman, Acting Associate Administrator, Office of Public Affairs; and Jahan Wilcox, Strategic Communications Advisor, Office of Public Affairs (Apr. 5, 2017, 4:15 PM) *in* EDF, *Newly Released Records Refer to Pruitt's Personal Involvement in Removal of Climate Information from EPA Website*, EDF: Press release archive (Jan. 29, 2018), https://www.edf.org/sites/default/files/2018.01.05-partial-production.pdf.

At the same time, EPA was soliciting comments on its proposal to repeal the Clean Power Plan. The removal of webpages related to climate and Clean Power Plan topics from the EPA website restricted the public's ability to formulate informed comments throughout the rulemaking process.[561] Thus, the public lacked the same "access to data and influential scientific information used to inform federal regulation"[562] which EPA claims to observe in its proposal.

The Administration has not rigorously pursued its purported goal of transparency in other contexts by limiting public and press access to Agency events and withholding key data underlying several recent rulemaking proceedings.

At the event where former Administrator Pruitt announced the proposal, reporters were not invited to attend.[563] Documents received in response to a Sierra Club FOIA request to the EPA reveal that the Administrator had requested press access and advertisement to the public be limited for other events.

For his speaking engagement at a Federalist Society event in March 2017, Pruitt's scheduling director asked that organizers not advertise to press directly and directed organized to tell media that the event "is not open to press and is off the record."[564] Emails also demonstrate that the Agency worked with a public relations firm to devise a plan to promote positive comments and censor negative comments on media from the Administrator's facility visits.[565]

EPA additionally failed to provide the public with access to data in key rulemakings and proceedings. For example, in EPA's rulemaking to repeal emissions requirements for glider vehicles, engines, and kits, commenced in November 2017, the Agency failed to release the underlying reports and data before the public comment period closed.[566] At this date, EPA still has not released data used in a key study cited in the Agency's proposal.

In the words of the proposal, EPA acted in contravention of its goals of "better informing the public," "enhancing the public's ability to understand and meaningfully participate in the

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[561] Environmental Data & Governance Initiative on EPA's Proposal, *Repeal of Carbon Pollution Emission Guidelines for Existing Stationary Sources: Electric Utility Generating Units*, 82 Fed. Reg. 48,035 (Apr. 26, 2018), *available at* https://envirodatagov.org/edgi_cpp_proposed_rule_comments_042618/.
[562] 83 Fed. Reg. 18,768, 18,768 (Apr. 30, 2018).
[563] Miranda Green, *Pruitt signs proposed rule to erase 'secret science' from EPA*, The Hill (Apr. 24, 2018, 2:40 PM), http://thehill.com/policy/energy-environment/384636-pruitt-signs-proposed-rule-to-erase-secret-science-from-agency.
[564] Email from Juli Nix, Director of Conferences, Federalist Society, to Millan Hupp, Director of Scheduling and Advance, EPA (Mar. 17, 2017, 12:30 PM)(on file with Sierra Club), https://www.documentcloud.org/documents/4453164-Pruitt-Sierra-Club-NYT-Foia.html#document/p29/a422141.
[565] Email from Gus Wagner, Partner and Creative Dir., ARC Media, forwarded to Barry Hart, CEO, Nat'l Rural Electric Coop. Ass'n; Amy Graham, Dir. of Commc'n, EPA; Tate Bennett, Assoc. Adm'r, Office of Public Engagement and Envvtl. Educ.; Joe Wilkinson, Sr. Vice Pres., Assoc. Electric Coop. (Apr. 18, 2017).
[566] EDF Supplemental Comment on EPA's Proposed Rule, *Repeal of Emission Requirements for Glider Vehicles, Glider Engines, and Glider Kits*, 82 Fed. Reg. 53,442 (Mar. 11, 2018), *https://www.edf.org/sites/default/files/content/EDF%20Third%20Supplemental%20Comment%20re%20TTU%20Study%203.11.18.pdf*.

regulatory process," and "ensur[ing] that its decision-making is marked by independence, transparency, clarity, and reproducibility" as it proceeded through rulemakings that "will affect the public" and where "the public is likely to bear the cost of compliance."[567]

VIII. The Proposal Violates Procedural Requirements of the APA, CAA, and Other Statutes and Executive Orders

The proposed rule fails to meet even the most basic procedural and substantive obligations. The Administrative Procedure Act (APA) requires that the "opportunity for comment must be a meaningful opportunity," and "[t]hat means enough time with enough information to comment and for the agency to consider and respond to the comments." *Prometheus Radio Project v. FCC*, 652 F.3d 431, 450 (3d Cir. 2011) (internal citation and quotation marks omitted). *See also Am. Hosp. Ass'n v. Bowen*, 834 F.2d 1037, 1044-45 (D.C. Cir. 1987) (noting the "obvious importance of the [APA's] policy goals of maximum participation and full information."). For its part, the Clean Air Act (CAA) "requires a much more detailed notice of proposed rulemaking than does the APA." *Union Oil Co. of Cal. v. EPA*, 821 F.2d 678, 682 (D.C. Cir. 1987); *see Small Refiner Lead Phase-Down Task Force v. EPA*, 705 F.2d 506, 550 (D.C. Cir. 1983) ("[T]he additional notice requirements in § 307(d)(3) suggest that Congress intended agency notice under the Clean Air Act to be more, not less, extensive than under the APA."). Executive Order 13563 underscores these obligations requiring that to promote "open exchange of information and perspectives among State, local, and tribal officials, experts in relevant disciplines, affected stakeholders in the private sector, and the public as a whole," agencies "shall endeavor to provide the public with an opportunity to participate in the regulatory process."[568]

Moreover, notice has to be provided by the agency; it cannot be bootstrapped from the public comments.[569] The reasons are evident: there is no requirement for parties to monitor all of the thousands or tens of thousands of submitted comments in order to guess the issues on which to comment.[570] A contrary rule "would turn notice into an elaborate treasure hunt, in which interested parties, assisted by high-priced guides (called 'lawyers'), must search the record for the buried treasure of a possibly relevant comment."[571]

Drafting these comments has entailed a great deal of guesswork. The comments of EDF or any other commenter on a particular issue thus should not be taken to mean that EPA provided sufficient notice of that issue.

The proposed rule lacks essential elements needed to understand it, rendering the opportunity for comment meaningless. The Proposal contains vague and contradictory statements about its actual substance and effect, fails entirely to analyze and disclose its costs

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[567] 83 Fed. Reg. 18,768, 18,768-9 (Apr. 30, 2018).
[568] Exec. Order 13563 § 2.
[569] *Small Refiner Lead Phase-Down Task Force v. EPA*, 705 F.2d 506, 547 (D.C. Cir. 1983); *Shell Oil Co. v. EPA*, 950 F.2d 741, 760-61 (D.C. Cir. 1991); *CSX Trans. v. Surface Transp. Bd.* 584 F.3d 1076, 1082 (D.C. Cir. 2009); *City of Waukesha v. EPA*, 320 F.3d 228, 234 (D.C. Cir. 2003).
[570] *Am. Fed'n of Labor v. Donovan*, 757 F.2d 330, 340 (D.C. Cir. 1985); *Fertilizer Inst.v. EPA*, 935 F.2d 1303, 1312 (D.C. Cir. 1991).
[571] *Small Refiner Lead Phase Down*, 705 F.2d at 550.

and benefits, and is littered with vague references to entire websites and executive branch departments. The cursory reasoning and wholly inadequate record offered in support of the proposed rule prevents stakeholders from engaging with the agency on its rationale for the proposed action and its costs and benefits, or offering contrary evidence. Finally, EPA has not provided any basis whatsoever to warrant the gross inadequacies of the proposed rule and the process to consider it. With such a deeply deficient basis for action, the only legally viable course is to withdraw the Proposal.

A. The Proposed Rule is a Binding, Legislative Rule and Subject to the Requirements of the APA

The Administrative Procedure Act, the Clean Air Act, and other federal statutes proscribe procedures that must be followed in agency rulemaking, and which EPA has failed to meet in its Proposal. This proposed rule does not fit into any of the exceptions the APA provides for the procedural requirements of rulemaking—it is neither an interpretive rule, general statement of policy, or a rule of agency organization, procedure or practice.[572]

The proposed rule does not purport to clarify or explain an already existing statute or rule, and thus is not an interpretive rule.[573] The proposed rule is not a general statement of policy, because it establishes a standard of conduct, which has the force of law. It uses mandatory language indicating a requirement: "When promulgating significant regulatory actions, the Agency *shall* ensure that dose response data and models underlying pivotal regulatory science are publicly available in a manner sufficient for independent validation."[574] Unlike a general statement of policy, which "does not establish a 'binding norm,'. . . [and] is not finally determinative of the issues or rights to which it is addressed," EPA here makes no qualifications that it has any leeway to not follow the Proposal's new requirements in all future regulatory actions.[575] The provision allowing the EPA Administrator to grant exceptions in a limited number of cases does not turn this rule into a general statement of policy because it also binds the Administrator's discretion, allowing deviation from the policy only when they make specific findings.[576] EPA has not indicated that "in subsequent proceedings it will thoroughly consider not only the policy's applicability to the facts of a given case but also the underlying validity of the policy itself," but seems poised to apply the policy in all instances—granting exceptions only in limited circumstances where compliance is deemed impracticable.[577] It nowhere indicates that EPA may reassess in each case whether following this rule is the best means to achieve scientific integrity as it undertakes regulatory action. The Proposal has other indications of a binding rule, including that EPA intends to codify it in the Code of Federal Regulations, and EPA has itself characterized the Proposal as a binding rule.[578]

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[572] 5 U.S.C. § 553.
[573] *Guardian Fed. Sav. & Loan Asso. v. Fed. Sav. & Loan Ins. Corp.*, 589 F.2d 658, 665 (D.C. Cir. 1978).
[574] Proposed Rule, 83 Fed. Reg. at 18,773 (emphasis added); *Pac. Gas & Elec. Co. v. Fed. Power Com.*, 506 F.2d 33, 38-39 (D.C. Cir. 1974).
[575] *Pac. Gas & Elec. Co. v. Fed. Power Com.*, 506 F.2d 33, 38 (D.C. Cir. 1974).
[576] Proposed Rule, 83 Fed. Reg. at 18,774.
[577] *Pac. Gas & Elec. Co. v. Fed. Power Com.*, 506 F.2d 33, 39 (D.C. Cir. 1974).
[578] Robinson Meyer, *Scott Pruitt's New Rule Could Completely Transform the EPA*, The Atlantic (Apr. 24, 2018), https://www.theatlantic.com/science/archive/2018/04/how-the-epas-new-secret-science-rule/558878/ (as

This rule is also not a rule of agency organization, procedure or practice, for purposes of the APA. Agency actions in this category are those "that do not themselves alter the rights or interests of parties, although it may alter the manner in which the parties present themselves or their viewpoints to the agency."[579] An agency action that "trenches on substantial private rights and interests" does not fall under this exemption.[580] By restricting the scientific studies on which EPA may base final significant regulatory actions, EPA severely limits parties from relying on excluded studies in advocating for particular safeguards. In the preamble, EPA makes clear that the rule is about "EPA's regulatory actions" and underlying conclusions.[581] Because the rule substantively impacts agency conclusions and regulations, it impacts private rights and interests. The rule does not allow private individuals to submit for consideration (or renders such submittal a nullity) studies that they would have been permitted to prior to the proposed rule, thus impacting the substantive standards that EPA is able to justify setting—which has implications for the regulated community as well as for public health. The Proposal "encodes a substantive value judgment or puts a stamp of approval or disapproval on a given type of behavior" by requiring regulatory actions to be supported only by certain scientific information deemed acceptable by the proposed rule.[582]

In *CropLife Am. v. E.P.A.*, the Court held that a similar rule promulgated by EPA, barring third-party human studies from agency consideration during pesticide registrations was a binding regulation because it used "clear and unequivocal language" reflecting "an obvious change in established agency practice" that created a "binding norm."[583] The Court stated: "EPA's stated rule is binding on petitioners, who are now barred from relying on third-party human studies (even in cases where such studies formerly were approved), and is binding on the agency because EPA has made it clear that it simply 'will not consider' human studies."[584] Similarly, the Proposal appears to bind EPA to not consider scientific information it could consider before, unless it falls under certain narrow, ambiguously defined exceptions, and binds the public and organizations such as EDF who can no longer submit studies to EPA that EPA would previously have been required to consider as part of the rulemaking process.

B. The Proposal is Subject to the Procedural Requirements of the Clean Air Act.

Administrator Pruitt signed the Proposal, he stated: "This is not a policy. This is not a memo. This is a proposed rule.").

[579] *Batterton v. Marshall*, 648 F.2d 694, 707 (D.C. Cir. 1980).

[580] *Batterton v. Marshall*, 648 F.2d 694, 708 (D.C. Cir. 1980).

[581] 83 Fed. Reg. 18,769.

[582] *Am. Hosp. Asso. v. Bowen*, 834 F.2d 1037, 1047 (D.C. Cir. 1987). *See also Pharm. Mfrs. Asso. v. Finch*, 307 F. Supp. 858, 865 (D. Del. 1970) (finding that a regulation promulgating new criteria for clinical investigations that will meet the standards of evidence necessary to demonstrate the effectiveness of drug products, and excluding certain kinds of clinical investigations, was not merely a procedural rule, because they "did effect a material narrowing of the range of evidence which previously had been considered relevant in evaluating a drug's efficacy. Because of the important clarification of acceptable testing standards effected by the September regulations and because of the substantial impact of these regulations on the drug industry. . . . ")

[583] 329 F.3d 876, 881 (D.C. Cir. 2003).

[584] *Id.*

Section 307(d) applies to "such. . . actions as the Administrator may determine."[585] EPA claims to take this action under "authority of the statutes it administers. . . including Clean Air Act sections 103, 301(a)."[586] By issuing this Proposal through notice and comment procedures, Administrator Pruitt appears to have determined that 307(d) procedures apply.

Even without that invocation, the proposed rule is subject to these procedural requirements because it materially impacts many of the actions delineated in 307(d)(1) to which the CAA rulemaking procedures explicitly apply. The Proposal applies to "significant regulatory actions," which many of these actions are. The CAA requires science-based decision-making that the Proposal will materially affect. For example, by restricting the science EPA may rely on in regulatory actions, the Proposal materially impacts residual risk determinations for hazardous air pollutants (§ 307(d)(1)(C)), standards for mobile source air toxics (§ 307 (d)(1)(K)), and residual risk standards for municipal solid waste combustors (§ 307(d)(1)(D)).[587]

This proposed rule directly affects EPA's setting and review of National Ambient Air Quality Standards (NAAQS),[588] the promulgation or revision of which is subject to the CAA rulemaking requirements.[589] Section 108(a) of the Clean Air Act requires the Administrator to set air quality criteria for air pollutants that "reflect the latest scientific knowledge." This Proposal amends the science EPA can consider for air quality criteria. Under CAA section 109 EPA must use the air quality criteria to set primary and secondary NAAQS and periodically review them—which EPA is currently doing for Particulate Matter.[590] In the Proposal, EPA cites *Am. Trucking Ass'ns v. EPA*, 283 F.3d 355, 358 (D.C. Cir. 2002) as an example of an instance where EPA relied on a scientific study where the underlying data was not publicly available. EPA states that under the Proposal use of such science would be "preclude[d]".[591] In *Am. Trucking Ass'ns* the Court upheld EPA's use of key studies underlying the NAAQS for PM. Under the Proposal, EPA would not have been permitted to use those studies, and it is unclear how the Proposal will affect EPA's reliance on these studies as it undertakes its review. This demonstrates how this Proposal would have an immediate impact on EPA NAAQS-setting under the CAA. EPA is thus subject to the CAA 307(d) procedural requirements for this Proposal.

C. EPA Has Failed to Provide a Properly Developed Docket and Record as Required by the APA and CAA and Has Thereby Violated the Notice Requirements of these Statutes

EPA has failed to provide a properly developed record in support of the proposed rule. EPA has not identified sufficient supporting evidence in the Proposal or in its docket and has failed to provide adequate notice of the supporting evidence for the public to respond to

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[585] 42 U.S.C.S. § 7607(d)(1)(V).
[586] 83 Fed. Reg. at 18,769.
[587] 83 Fed. Reg. at 18,773.
[588] CAA Section 108(a).
[589] CAA Section 307(d)(1)(A).
[590] *See Release of the Final Integrated Review Plan for the National Ambient Air Quality*, 81 Fed. Reg. 87,933 (Dec. 6, 2016).
[591] 83 Fed. Reg. at 18,769 n. 3.

meaningfully, as the Administrative Procedure Act, the Clean Air Act, and other substantive statutes require.

Under the APA, agencies must base their actions on examination of the facts, "the agency must examine the relevant data and articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'"[592] The factual determination underlying the agency decision must be based on substantial evidence and will be set aside "if the agency 'relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.'"[593]

Rulemaking under the Clean Air Act is subject to the same general requirements of statutory conformity and reasoned decision-making derived from the APA and basic principles of administrative law. Clean Air Act rules cannot be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right," or "without observance of procedure required by law."

As noted in Appendix A and below in Section VIII.D EPA's citations for support in the Proposal are vague and uninformative, and even where the particular citation can be identified and located, it is often not clear how EPA thinks the citation supports the Proposal. This does not meet the standards of the APA and CAA.

Additionally, EPA has failed to meet the docket requirements of the CAA. CAA section 307(d)(3) requires that publication of the proposed rule in the Federal Register include a summary of the factual data on which the proposed rule is based, the methodology used in obtaining the data and in analyzing the data, and the major legal interpretations and policy consideration underlying the proposed rule. It also requires the agency to place "[a]ll data, information, and documents. . . on which the proposed rule relies" in the rulemaking docket on the date of publication of the proposed rule.[594] The undifferentiated citation of articles and policies, most of which contradict the Proposal or otherwise offer no support for it, fails abjectly to satisfy these requirements.[595] Any document that becomes available after the proposed rule

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[592] *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43-44, (1983).

[593] *Cablevision Sys. Corp. v. FCC*, 597 F.3d 1306, 1310 (D.C. Cir. 2010).

[594] CAA Section 307(d)(3).

[595] *See Kennecott v. EPA*, 684 F.2d 1007, 1018 (D.C. Cir. 1982)("Section 307(d)(3) requires that notice of proposed ... regulations be accompanied by a statement of their basis and purpose, including the factual data on which the proposed regulations are based, the methodology used in obtaining and analyzing the data, and the major legal interpretations and policy considerations underlying the proposed regulations. . . . Though EPA states in its preamble to the final regulations that its current eligibility test is based upon a closure policy adopted by EPA before 1977, and that it has used financial tests similar to the present closure test under the agency's existing policy, no documents embodying those tests or demonstrating the methodology used before 1977 were ever placed in the docket. The only document in the docket purporting to explain that a closure test was ever employed by EPA was a memorandum in which EPA economist Hale sets forth his recollection that such a test had been used before 1977 to determine whether smelters would be permitted to rely upon dispersion techniques to meet the ambient standards. That memo, dated August 17, 1979, was placed in the docket on March 12, 1980, approximately eleven months after

has been published and that is of central relevance to the rulemaking must also be placed in the docket as soon as possible after its availability.[596] The agency must allow enough time for participants in the rulemaking to respond to those documents with comments.[597]

As of the date of the publication of the Proposal, the docket at regulations.gov contained only the following 12 documents: (1) OIRA Review Start Document (Apr. 17, 2018); (2) OIRA Review Conclusion Document (Apr. 23, 2018); (3) White House Memorandum on Scientific Integrity (Mar. 9, 2009); (4) *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies*; Republication, 67 Fed. Reg. 8,452 (Feb. 22, 2002); (5) Exec. Order 13,777, *Enforcing the Regulatory Reform Agenda*, 82 Fed. Reg. 12,285 (Feb. 24, 2017); (6) EPA, *Plan to Increase Access to Results of EPA-Funded Scientific Research* (Nov. 29, 2016); (7) OMB Memorandum M-05-03 on Issuance of OMB's "Final Information Quality Bulletin for Peer Review" (Dec. 16, 2018); (8) EPA, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency* (Oct. 2002); (9) Exec. Order 13,563, *Improving Regulation and Regulatory Review*, 76 Fed. Reg. 3,821 (Jan. 18, 2011); (10) Exec. Order 16, 093, *Promoting Energy Independence and Economic Growth*, 82 Fed. Reg. 16,093 (Mar. 28, 2017); (11) OMB Memorandum M-13-13: Open Data Policy-Managing Information as an Asset (May 9, 2013); (12) Commission on Evidence-Based Policymaking, *The Promise of Evidence-Based Policymaking* (Sep. 2017).

This clearly is not enough to meet the APA's or CAA's requirements. Aside from the drafts of the proposed rule submitted to OIRA, each of these documents was a pre-existing memorandum, policy document, or executive order that contains no specific analysis—factual, legal, policy or otherwise—that pertains to the impacts of or at all justifies *this* proposed rule. While EPA in the proposed rule cites to some of these documents as purportedly being consistent with these prior policies, *see, e.g.*, 83 Fed. Reg. at 18,769-70, as is discussed in Section II and in Appendix A, these policies do not in fact provide any basis for the Proposal. The record that EPA provides clearly fails to support its proposed action. Some of the factual data, legal interpretations, and policy considerations that EPA has not sufficiently provided evidence for include: the number of scientific studies that would be precluded from consideration under the Proposal; whether there are fields of research where the Proposal would result in insufficient scientific information available for EPA to meet its statutory duties; how EPA will address the substantial privacy concerns implicated by the Proposal; how application of this Proposal will impact substantive agency actions; what the costs of implementing this Proposal are if EPA intends to not just exclude studies from consideration where too costly to provide access, etc.

EPA, for instance, includes Executive Order 13,563 in the docket to support its statement that "[t]he best available science must serve as the foundation of EPA's regulatory actions."[598] While Executive Order 13,563 makes that statement, it does not support EPA's Proposal, which

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the close of the public comment period, and reveals neither the actual tests nor the methodology used by EPA. The failure of EPA to observe the procedures mandated by §§ 307(d)(3) and 307(d)(6) was thus arbitrary and capricious.")

[596] CAA Section 307(d)(4).

[597] *Sierra Club v. Costle*, 657 F.2d 298, 352 (D.C. Cir. 1981); *Union Oil Co. v. EPA*, 821 F.2d 678, 683 (D.C. Cir. 1987).

[598] 83 Fed. Reg. at 18,769 n. 1.

as explained above, hinders EPA's use of the best available science. EPA provides no evidence or explanation in the docket or Proposal for why EPA believes this policy would further that goal. The executive order only states that agencies should make available to the public the scientific or technological *findings or conclusions* on which rules rely, as opposed to underlying raw data that EPA has targeted with this Proposal. Meanwhile, EPA blatantly violates the executive order's provisions requiring agencies to weigh costs and benefits; to write regulations that are easy to understand; and to provide the scientific and technical findings underlying the rule for the public to comment on.

Section 307(d)(3) of the CAA requires that "[a]ll data, information, and documents … on which the proposed rule relies shall be included in the docket on the date of publication of the proposed rule." Many items that EPA cites to in the Proposal as providing a basis for the proposed rule do not appear in the docket. For example, EPA states: "The proposed rule takes into consideration the policies or recommendations of third party organizations who advocated for open science."[599] In a footnote, EPA provides: "These include policies and recommendations from: The Administrative Conference of the United States' Science in the Administrative Process Project; National Academies' reports on *Improving Access to and Confidentiality of Research Data, Expanding Access to Research Data,* and *Access to Research Data in the 21st Century;* the Health Effects Institute; Center for Open Science; members of the Risk Assessment Specialty Section of the Society of Toxicology, the Dose Response Section of the Society for Risk Analysis, and the International Society for Regulatory Toxicology and Pharmacology; and the Bipartisan Policy Center's Science for Policy Project."[600] Many of these policies and recommendations did not appear in the docket on the data of publication of the Proposal and still do not appear in the docket—a clear violation of the CAA—nor are the specific documents or reports even identified or properly cited so that they may be tracked down. This is evidently prejudicial to commenters—it undermines commenters ability to submit meaningful feedback when the agency is hiding the ball in this manner.

These policies and recommendations are not easily identifiable on their own either, even after significant internet research. This is also true of footnote 16, where EPA lists a number of agencies to support its claim that the federal government is already implementing solutions to data disclosure.[601] EPA cites, for example, the National Institute of Standards of Technology. NIST has numerous policy documents on protecting privacy concerns and keeping data secure as well as its own internal policies on releasing data. It is hard to see how any are relevant here, but without a particular cite the public is denied even a chance to respond to whatever EPA is trying to use as support—or must respond to *everything* that might be being referenced, creating a burdensome task. Throughout these comments, as we attempt to respond to EPA's Proposal, we have been very practically limited by our inability, even after much research and consideration, to be fully certain we have identified the appropriate policies to respond to. This presents a situation that the CAA's docket requirement was exactly formulated to prevent.

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[599] 83 Fed. Reg. at 18,770.
[600] 83 Fed. Reg. at 18,770 n. 10.
[601] 83 Fed. Reg. at 18,770 n. 16.

On May 25, 2018, EPA added a memorandum to the docket for this rulemaking.[602] This memorandum contains hyperlinks apparently intended to accompany various citations in the footnotes of the Proposal. This document does not cure the former procedural defect, as the CAA requires information the proposed rule relies on to be placed in the docket on the day the proposed rule is published.[603] Further, these hyperlinks still link ambiguously to various documents and agency websites without providing any information about what specifically EPA intends to cite or how the cited information is being used or considered by EPA. Additionally, simply adding such a document to the docket does not provide adequate notice to the public. Someone who had access only to the proposed rule and was not carefully monitoring the docket would have no indication or notice of this new document.

Either EPA is failing to comply with the CAA's requirements by failing to include in the docket factual data, legal interpretations, and policy considerations that support the Proposal, or these supporting items do not exist, deeming this rulemaking completely arbitrary—in either case the Proposal fails to meet the standards of the APA and CAA. Under the CAA the rulemaking docket "must provide the entire basis for the final rule and the exclusive record for judicial review," this docket clearly cannot support a final rule.[604]

D. The Proposal is too Vague for Meaningful Comment.

Section 553 of the APA, 5 U.S.C. § 553(b)(3), requires that an agency proposing a rule "provide sufficient factual detail and rationale for the rule to permit interested parties to comment meaningfully."[605] The Clean Air Act requires even more, that the Federal Register notice be accompanied by a statement of basis and purpose that includes a summary of the factual data on which the proposed rule is based, the methodology used in obtaining the data and in analyzing the data; and the major legal interpretations and policy considerations underlying the proposed rule.[606] As discussed above, all data, information, and documents on which the proposed rule relies must be included in the docket on the date of publication of the proposed rule.[607]

These core requirements are "designed (1) to ensure that agency regulations are tested via exposure to diverse public comment, (2) to ensure fairness to affected parties, and (3) to give affected parties an opportunity to develop evidence in the record to support their objections to the rule and thereby enhance the quality of judicial review."[608] In addition, "a chance to comment … [enables] the agency [to] maintain[] a flexible and open-minded attitude towards its

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[602] EPA Memorandum RE: Omitted Hyperlinks for Footnotes in the Proposed Rule (May 25, 2018), EPA-HQ-OA-2018-0259-0812.
[603] Section 307(d)(3).
[604] *Union Oil Co. of California v. EPA.*, 821 F.2d 678, 681-82 (D.C. Cir. 1987).
[605] *United States Telecom Assn. v. FCC*, 825 F.3d 674, 700 (D.C. Cir. 2016) (quoting *Honeywell Intl., Inc. v. EPA*, 372 F.3d 441, 445 (D.C. Cir. 2004) (internal quotation marks omitted).
[606] 42 U.S.C. § 7607(d)(3).
[607] 42 U.S.C. § 7607(d)(3).
[608] *Int'l Union, United Mine Workers of Am. v. Mine Safety and Health Admin.*, 407 F.3d 1250, 1259 (D.C. Cir. 2005).

own rules,"[609] and "avoid[s] the inherently arbitrary nature of unpublished ad hoc determinations."[610] The "notice required by the APA … must disclose in detail the thinking that has animated the form of a proposed rule and the data upon which that rule is based …. [A]n agency proposing informal rulemaking has an obligation to make its views known to the public in a concrete and focused form so as to make criticism or formulation of alternatives possible." *Home Box Office, Inc. v. FCC*, 567 F.2d 9, 35-36 (D.C. Cir. 1977); *see also Horsehead Res. Dev. Co., Inc. v. Browner*, 16 F.3d 1246, 1268 (D.C. Cir. 1994) ("[A]n agency must describe the range of alternatives being considered with reasonable specificity. Otherwise, interested parties will not know what to comment on, and notice will not lead to better-informed agency decision-making.") (internal citations and quotation marks omitted).

The failure to include critical documents relevant to the proposed rule in the docket, as required by the Clean Air Act, itself constitutes a notice violation because "absence of those documents, or of comparable materials. . . makes impossible any meaningful comment on the merits of EPA's assertions."[611] By failing to provide a more developed docket, EPA is frustrating the terms and purposes of these statute's notice requirements. These procedures are in place to form a "specific" proposal that can serve as a "focus for comments," *Small Refiner Lead Phase-Down Task Force v. EPA*, 705 F.2d 506, 548-49 (D.C. Cir. 1983); *see Home Box Office, Inc. v. FCC*, 567 F.2d 9, 36 (D.C. Cir. 1977) (agency must "make its views known . . . in a concrete and focused form so as to make criticism or formulation of alternatives possible"). Because EPA has not provided supporting evidence, has not included key items it points to as major considerations underlying the Proposal, and has generally presented a vague and unspecified proposed rule and docket, EDF and the public are hindered in our ability to provide specific comment focused on the underpinnings of the Proposal, because we do not know and can only guess as to what they are.[612]

Even the text of EPA's proposed rule and the statement of basis and purpose fails to provide the requisite notice to allow meaningful comment. At the most fundamental level, it contains vague and contradictory statements about the actual effect of the Proposal. The Proposal generally appears to make its requirements mandatory—i.e., failure to make information publicly available will preclude the agency from relying on the study at all. *See* 83 Fed. Reg. at 18,769 n. 3 ("EPA is proposing to exercise its discretionary authority to establish a policy that would preclude it from using such data in future regulatory actions."); *id.* at 18,771 ("the regulatory text would impose requirements"); *see also id.* at 18,769 ("EPA *will* ensure that the data and models underlying the science is publicly available…") (emphasis added) and proposed section 30.5 ("When promulgating significant regulatory actions, the Agency shall ensure that does response data and models underlying pivotal regulatory science are publicly available in a manner sufficient for independent validation"). In a few places, however, the Proposal makes it sound as if its aims are more aspirational. *See id.* at 18,770 ("Where *available and appropriate*, EPA will use peer-reviewed information, standardized test methods, consistent data evaluation procedures,

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[609] *McLouth Steel Prods. Corp. v. Thomas*, 838 F.2d 1317, 1325 (D.C. Cir. 1988) (internal citation and quotation marks omitted).

[610] *United States v. Reynolds*, 710 F.3d 498, 519-20 (3d Cir. 2013).

[611] *Kennecott Corp. v. EPA*, 684 F.2d 1007, 1018 (D.C. Cir. 1982).

[612] "Without a readily accessible statement of the agency's rationale, interested parties [could not] comment meaningfully during the rulemaking process." *Ne. Md. Waste Disposal Auth. v. EPA*, 358 F.3d 936, 949 (D.C. Cir. 2004).

and good laboratory practices to ensure transparent, understandable, and reproducible scientific assessments.") (emphasis added); *id.* at 18,772 ("The proposed rule directs EPA to make *all reasonable efforts* to" make data publicly available, but "does not compel the Agency to make that information available where it concludes after all such reasonable efforts that doing so in way [sic] that complies with the law and appropriate protections is not possible.") (emphasis added); *see also id.* at 18,768 ("EPA *should* ensure that the data underlying those are publicly available…") (emphasis added). The difference between a *requirement precluding* use of science and making *all best efforts* to make data publicly available is enormous.

To the extent EPA intends to propose a rule that would *preclude* use of science, as it appears the Proposal would do, the proposed rule is further flawed because it contains no analysis of how that would affect regulations. How many studies does EPA typically rely on in promulgating regulations? What percentage of these would meet EPA's new requirements? For those that do not, how many could not meet these requirements for patient privacy, confidential business information, or other reasons? How would EPA set standards if it must rely on many fewer studies? Would EPA be precautionary in the face of less evidence? Would EPA delay promulgating regulations in order to comply with this new mandate? How does this mandate interact with statutory deadlines or statutory requirements that EPA look at a wide range of science? None of these very basic questions are addressed in the proposed rule and without answering them, it is impossible for the public to assess the import and likely consequences of the Proposal. Even more basically, the agency gives no notice as to the Proposal's impacts, its costs, its benefits, why it applies only to regulatory requirements but not to any regulatory actions (like licensing or permitting) that confer a benefit, substantive and procedural criteria for adjudicating waivers, or even the legal theory under which the Proposal issues—the plaintive solicitation for comment as to "additional or alternative sources" of authority, 83 Fed. Reg. at 18771, does not suffice.

To the extent the Proposal is intended to solicit comment on how EPA may make reasonable efforts to make data publicly available it is also unlawfully vague. The proposed rule includes numerous footnotes referencing entire websites or even Departments of the Executive Branch. For example, the Proposal claims that "EPA believes that concerns about access to confidential or private information can, in many cases, be addressed through the application of solutions commonly used across some parts of the Federal government."[613] To support this proposition, EPA remarkably cites (without any further elaboration or explanation in the proposal itself) to "examples from the U.S. Department of Health and Human Services, National Institute of Standards and Technology, U.S. Department of Education, and the U.S. Census Bureau."[614] *See Small Lead Refiner Phase Down,* 705 F. 2d at 548 (requirement that comments are to raise issues with "reasonable specificity" applies equally to the agency giving notice). For example, it is not possible to identify whether the sources referenced support EPA's claim that there are approaches available to address the serious privacy issues raised by the Proposal—without providing the specific policies and recommendations, a public commenter has no way of knowing whether they are consistent or why EPA believes them to be consistent. It is impossible to respond in a meaningful way without significant guesswork.

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[613] Proposed Rule, 83 Fed. Reg. at 18,770.
[614] *Id.* at 18,770 n. 16.

Similarly, in footnote 10, where EPA lists a number of organizations whose "policies and recommendations" the Proposal allegedly took under consideration—no explanation is provided.[615] In addition, in the proposed rule EPA fails to adequately define key terms like "validation", "independence", "reproducibility," "replication," and "uncertainty," while also citing a "replication crisis" in science. It is important that these terms are defined clearly as these terms are not defined consistently across the scientific community nor governments—which has implications for the scope and purview of the proposed rule.

This amount of information is wholly insufficient to allow a public commenter to provide meaningful comments about these issues.

Courts have been reluctant to find that important information appearing solely in the footnote of a rulemaking document satisfied the notice requirement of the APA, holding that "an agency may not turn the provision of notice into a bureaucratic game of hide and seek."[616] Referencing a key document without further discussion in the rulemaking document itself, and without incorporating it by reference or publishing it in the Federal Register, also does not satisfy the notice requirements of the APA.[617] Subsequent publication of the document may not be enough to cure a defect of notice where an important issue is "belied by the obscurity of the footnote intended to give notice" and further agency procedure is required to provide the public with "the opportunity to comment on a significant part of the agency's decisionmaking process as required by section 553."[618] Thus, the undifferentiated citations in the footnotes of the Proposal do not give adequate notice for public comment.[619]

E. EPA Must Comply With Other Requirements of the Clean Air Act

As discussed above, the Proposal impacts EPA's process for setting NAAAQs in material ways by amending the scientific information that can be used as air quality criteria. Under the CAA air quality criteria cannot be amended without review by the Clean Air Science Advisory Committee (CASAC).[620] Thus, EPA must submit this proposal to CASAC for review, consider

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[615] 83 Fed. Reg. at 18,770. n. 10 ("These include policies and recommendations from: The Administrative Conference of the United States' Science in the Administrative process Project; National Academies' reports on *Improving Access to and Confidentiality of Research Data, Expanding Access to Research Data,* and *Access to Research Data in the 21st Century;* the Health Effects Institute; Center for Open Science; members of the Risk Assessment Specialty Section of the Society of Toxicology, the Dose Response Section of the Society for Risk Analysis, and the International Society for Regulatory Toxicology and Pharmacology; and the Bipartisan Policy Center's Science for Policy Project.)

[616] *MCI Telcommunications Corp. v. FCC*, 57 F.3d 1136, 1142 (D.C. Cir. 1995).

[617] *PPG Indus., Inc. v. Costle*, 659 F.2d 1239, 1249-50 (D.C. Cir. 1981).

[618] *PPG Indus., Inc. v. Costle*, 659 F.2d 1239, 1250 (D.C. Cir. 1981).

[619] *See, e.g., Chamber of Commerce v. SEC,* 443 F. 3d 890, 899 (D.C. Cir. 2006); *Jackson v. Des Moines Mun. Housing Agency*, No. 4:07-cv-00438-HDV, 2008 U.S. Dist. LEXIS 125003, at *8-9 (S.D. Iowa June 4, 2008); *Billington v. Underwood,* 613 F.2d 91, 94 (5th Cir. 1980) ("Such a statement must be sufficiently specific for it to enable an applicant to prepare rebuttal evidence to introduce at his hearing appearance."); *Edgecomb v. Housing Auth.,* 824 F.Supp. at 312, 314-15 (1993); *Driver v. Housing Auth.,* 713 N.W.2d 670,673 (Wis. Ct. App. 2006); *Owner-Operator Independent Drivers Ass'n, Inc. v. Federal Motor Carrier Safety Admin.*, 494 F.3d 188, 209 (D.C. Cir. 2007) ("It is certainly true that a notice can be "too general to be adequate.").

[620] CAA § 109(d)(2)(B).

their recommendations, and provide reasonable explanation for deviation from those recommendations.[621]

F. EPA Failed to Submit the Proposal to the SAB or to Consult with the Scientific and Technical Community

There is no indication that EPA consulted with the scientific and technical community—or even its own Science Advisory Board—before proposing to require that the underlying data and models be made publicly available for all pivotal regulatory science regardless of ethical, feasibility, or confidentiality constraints. As detailed in a June 28, 2018 letter from the chair of the SAB, the SAB learned of the rule only through a press event, federal register notice, and news articles.[622] The letter further explained that the proposed rule "was not identified as a major action in either of the Spring 2017 or Fall 2017 semi-annual Regulatory Agendas," and that SAB members "had no information regarding the timeline for finalizing the rule . . . ."[623] The letter also points out that "the precise design of the proposed rule appears to have been developed without a public process for soliciting input specifically from the scientific community," even though the proposed rule raises important scientific questions.[624]

Not surprisingly, the SAB concluded in its May 31, 2018 meeting that the Proposal merits SAB review because it "deals with issues of scientific practice and proposes constraints to the use of scientific studies in particular contexts."[625] Moreover, the SAB chair's June 28 letter raises a number of questions that echo the concerns we have detailed in our comments, including the feasibility of providing access to data and methods for already-completed studies; "legitimate confidentiality and privacy interests" that would counsel against providing "complete public access"; the costs and effort associated with implementing the Proposal; the relationship between the Proposal and previous EPA efforts to encourage transparency; and the need to consider "the multiple existing methods to assess the validity of prior epidemiologic studies" that "do not provide public access to data and analytic methods."[626]

EPA's failure to consult with the SAB is contrary to statute and to EPA's well-established practice. EPA must submit its Proposal to the SAB pursuant to the requirements of 42 U.S.C. § 4365(c)(1) (the Environmental Research Development Demonstration Authorization Act or "ERDAA"), which requires the Administrator to submit to the SAB any proposed criteria document, standard, limitation, or regulation, together with relevant scientific and technical information in the possession of the (EPA) on which the proposed action is based at the time it provides that proposal to another agency of the government for formal review. The SAB must

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[621] CAA § 109(d)(2)(B); 307(d)(3).
[622] Letter from Dr. Michael Honeycutt, Chair, Science Advisory Board, to Scott Pruitt, EPA Administrator (June 28, 2018), https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebReportsLastMonthBOARD/4ECB44CA28936083852582BB004ADE54/$File/EPA-SAB-18-003+Unsigned.pdf.
[623] *Id.*
[624] *Id.*
[625] *Id.*
[626] *Id.*

then review and comment on the proposal.[627] While the Administrator need not receive the SAB's final approval, the Administrator must consider the SAB's advice and comments.[628]

As the SAB chair's letter notes, EPA's "usual process" is to inform the SAB about the publication of the agency's semi-annual regulatory agenda and provide descriptions of actions that are contained in the agenda, including "available information regarding the science that is informing these agency actions."[629] That procedure was not followed here. In its evident zeal in the name of purported "transparency," EPA has ignored major statutory and regulatory requirements that provide *actual* transparency to the Clean Air Act's scientific review process.[630] Should EPA decide to move forward with this Proposal, it must first allow the SAB to complete its review and take into account the SAB's recommendations in any final rule.

G. EPA's Proposal Fails to Meet the Procedural Requirements of FIFRA

The Proposal lists FIFRA section 25 as an authority for the rulemaking.[631] The agency, however, has already failed to follow several required procedures for issuing a valid regulation under this section of FIFRA. FIFRA section 25 requires the agency to seek comments from the Secretary of Agriculture on all draft proposed regulations 60 days prior to signing a proposed regulation for publication,[632] and 30 days prior to publication for a final rule. If the Secretary of Agriculture provides comments, the Administrator must also respond in writing as part of the proposed rulemaking package.[633] FIFRA additionally requires EPA to publish a notice in the Federal Register simultaneously with the transmission of the proposed rule to USDA.[634] And the statute requires the agency to submit a copy of the proposed rule for comment to the Scientific Advisory Panel ("SAP"),[635] as well as a copy to the Agriculture Committees in the House and Senate *any time* the agency is required to consult with the Secretary of Agriculture.[636] This means that EPA here should have provided both committees and the SAP with a copy of the proposed regulation at least 60 days prior to publication of the Proposal in the Federal Register.

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[627] 42 U.S.C. §4365(c)(2).
[628] *See* H. Rep. No. 95-722 (95th Cong. 1st Sees. (1977) (Conference Report).
[629] Letter from Dr. Michael Honeycutt, Chair, Science Advisory Board, to Scott Pruitt, EPA Administrator (June 28, 2018).
[630] *See* Memorandum "Identifying EPA Planned Actions for Science Advisory Board Consideration of the Underlying Science" from Michael Goo, Assistant Administrator for Policy, Glenn Paulsen, EPA Science Advisor, and Vanessa Vu, Science Advisory Board Office Director (Dec. 27, 2012;) Memorandum from James Mihelcic, Chair, SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science to Members of the Chartered SAB and SAB Liaisons (Nov. 12, 2013) (explaining SAB Work Group process, where EPA sent to the SAB "short descriptions of major planned actions that were not yet proposed" and the SAB Work Group determined which of the actions merited their consideration in a public forum).
[631] 83 Fed. Reg. 18769.
[632] 7 U.S.C. 136w(a)(2)(A).
[633] 7 U.S.C. 136w(a)(2)(B).
[634] 7 U.S.C. 136w(a)(2)(D).
[635] 7 U.S.C. 136w(d)(1).
[636] 7 U.S.C. 136w(a)(3).

The agency did not comply with any of these requirements, and does not indicate that it will in any final rule. The Proposal is therefore unlawful.[637]

To be sure, in some instances the Administrator and Secretary may together agree to waive some of the consultation requirements among themselves,[638] but there is no indication that Administrator Pruitt did that with this Proposal. And even if the Administrator and Secretary later agree to waive the consultation requirement section 25(a)(2)(A) and (B), that waiver would not alter EPA's obligation to provide the SAP and the House and Senate Committees with a copy of the regulation. Nor would it change the fact that the Administrator illegally issued the Proposal without consulting the Secretary of Agriculture. A very serious consequence of these procedural mistakes is to deprive the agency of a full understanding of how the proposed rulemaking might affect the regulation of pesticides and thereby affect agriculture, human health, and the environment.[639] Therefore, the only lawful path forward here is for the Agency to withdraw the Proposal, consult with the entities required by FIFRA, and then subsequently re-notice the Proposal.

H. EPA's Proposal Fails to Meet the Procedural Requirements of the Safe Drinking Water Act, 42 U.S.C. § 300f Et Seq.

EPA cites the Safe Drinking Water Act as an authority for the Proposal, but has failed to comply with the procedural requirements of the statute. The SDWA provides authority to promulgate regulations at 42 U.S.C. 300g-1(d). Though EPA does not cite this particular section, it is the only provision of the SDWA that provides EPA with rulemaking authority. The SDWA requires the Administrator to consult with the Secretary of Health and Human Services and the National Drinking Water Advisory Council in proposing and promulgating regulations under this section. EPA has not met these requirements here, and as such cannot claim to be using SDWA authority to promulgate this rule.

I. EPA Unlawfully Failed to Consult with Other Agencies as Required by TSCA.

When promulgating the Proposal, EPA unlawfully failed to consult with other entities as required by TSCA. For example, consider the sole statutory authority EPA cites under TSCA—§ 10.

To the extent EPA acts under TSCA § 10, TSCA § 10 repeatedly directs EPA to consult, cooperate, and/or coordinate with the Secretary of Health and Human Services, and sometimes other agencies as well.[640] EPA has not identified any specific provision of TSCA § 10 that authorizes the proposed rule, and as noted above, no provision does. But if EPA acts under TSCA § 10, then EPA needs to comply with the requirements of whichever provision EPA

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[637] If finalized, the proposal will also have to be transmitted to the Secretary of the Senate and Clerk of the House of Representatives. See 7 U.S.C. 136w(a)(4). The rule does not become effective until 60 days after this rule or regulation is transmitted.
[638] 7 U.S.C. 136w(a)(2)(C).
[639] *See also,* Section II.D.8.
[640] 15 U.S.C. § 2609(a), (b)(2)(A), (b)(2)(B), (c), (d), (e), (g).

considers relevant. Most of the provisions of TSCA § 10 expressly require that EPA consult, coordinate, or cooperate with, at least, the Secretary of Health and Human Services (section 10(a), 10(b)(2)(A), 10(b)(2)(B), 10(c), 10(d), 10(e), 10(g)). For example, the provision that mentions "research and development results" states that EPA shall act "in consultation with the Secretary of Health and Human Services and other heads of appropriate departments and agencies."[641] EPA does not appear to have complied with any of the procedural requirements of TSCA § 10.

J. EPA Has Failed to Consult with the Science Advisory Committee on Chemicals

As discussed above, this proposed rule has severe implications for the implementation of TSCA. The Science Advisory Committee on Chemicals' purpose is "to provide independent advice and expert consultation, at the request of the Administrator, with respect to the scientific and technical aspects of issues relating to the implementation of this subchapter."[642] This rulemaking specifically involves "the scientific and technical aspects of issues relating to the implementation of [this Act]," yet there is no indication that the Administrator has consulted with the committee.[643] Congress specifically created this Committee to consult on these types of issues, and thus EPA is abusing its discretion to not consult with this Committee about a proposal that will so radically affect the scientific and technical aspects of issues relating to the implementation of TSCA.

K. EPA Has Failed to Provide Documents in Response to EDF's FOIA Requests

EDF currently has two Freedom of Information Act Requests directly related to the substance of this rulemaking pending at EPA, for which we have received *no* responsive documents thus far, despite the passage of the statutory deadlines for a response. The first request (No. EPA-HQ-2018-005636) was submitted on March 20, with a determination from EPA statutorily due by April 19—which has not been provided. EDF submitted a second request (No. EPA-HQ-2018-007397) on May 4. Given the lack of transparency and information around the basis for this rule, its impacts, and its true motivations, EDF and the public cannot provide informed comment on this rule without the public records that have been requested. For EPA to close the public comment period on this Proposal before all relevant records are released to the public is arbitrary and prevents our ability to meaningfully comment.

L. The OIRA Review Process for the Proposal Was Too Rushed to be Meaningful and EPA Has Not Sufficiently Coordinated with Other Federal Agencies

EPA did not provide enough time for the Office of Information and Regulatory Affairs ("OIRA") to meaningfully review the Proposal. Executive Order 12,866 requires agencies to

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[641] 15 U.S.C. § 2609(g).
[642] 15 U.S.C. § 2625(o)(2).
[643] 15 U.S.C. § 2625(o)(2).

submit all significant regulatory actions to OIRA.[644] This submission must contain "an assessment of the potential costs and benefits of the regulatory action" in addition to other analyses.[645] Executive Order 12,866 provides OIRA 90 days to review and return the draft regulatory action to the agency.[646] As indicated above, the Proposal gives scant consideration to the costs of the proposed action. The April 17, 2018 draft sent to OIRA for review contained *no* mention of cost and benefits of the Proposal at all.[647] It appears that OMB drafted the two paragraphs on costs that appear in the Proposal as published in the federal register.[648]

EPA transmitted the Proposal to OIRA on April 19, and OIRA's website indicates that its review concluded on April 23.[649] This is not nearly sufficient time for White House review of this far-reaching Proposal that raises important inter-agency issues. Further, media outlets report that there were discrepancies in the date when OIRA concluded its review of the proposed rule, suggesting that the date was backdated from April 25 to April 23 only after Administrator Pruitt signed the proposed rule on April 24.[650] The public record also shows OIRA convened no Executive Order 12,866 meetings in regards to this rule. EDF requested such a meeting on the morning of April 24; our request was not granted, even though the Proposal was still listed as under OIRA review.

The rushed process is particularly concerning given the proposed rule's complex cross-agency impacts. A letter from a group of Democratic senators to OIRA raising these concerns highlighted that, on average, OIRA review of EPA rules takes 55 days.[651] Given how bare-bones EPA's proposed rule was, lacking many of the elements required by Executive Order 12,866, it seems that OIRA should have required even more time to review the Proposal. Because this rule affects EPA's regulatory actions across program areas and statutes and interacts with the work of other agencies, as discussed more in Section II.D.8, adequate OIRA review was required to ensure consistency across the federal government. Certain other agencies base their standards on standards set by EPA. For example, FDA and EPA work together to promulgate advice on fish consumption, based on the reference dose calculated by EPA. The Proposal could thus have an impact on FDA's ability to promulgate advice on fish consumption sufficient to protect human health.[652] Thus, EPA's disregard of scientific evidence as it sets these standards will directly impact the sufficiency of standards set by these agencies.

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[644] Exec. Order 12,866, *Regulatory Planning and Review*, 58 Fed. Reg. 51,735 (Sept. 30, 1993).
[645] *Id.*
[646] *Id.*
[647] EO 12866 Proposal 2080-AA14 OIRA Review Start Document (Apr. 17, 2018), ID EPA-HQ-OA-2018-0259-0007.
[648] *Compare* EO 12866 Proposal 2080-AA14 OIRA Review Start Document (Apr. 17, 2018), ID EPA-HQ-OA-2018-0259-0007 *with* EO 12866 Proposal 2080-AA14 OIRA Conclusion Document (Apr. 23, 2018), ID EPA-HQ-OA-2018-0259-0006.
[649] OIRA, *OIRA Conclusion of EO 12866 Regulatory Review for Strengthening Transparency and Validity in Regulatory Science*, https://www.reginfo.gov/public/do/eoDetails?rrid=128014 (last accessed Aug. 16, 2018).
[650] *See* Sean Reilly, *OMB backdates completion date for 'secret science' review*, E&E News (Apr. 27, 2018), https://www.eenews.net/greenwire/2018/04/27/stories/1060080331.
[651] Letter from Senators Hassan, Carper, McCaskill, Markey, Harris, and Whitehouse to Neomi Rao, Administrator, OIRA (May 9, 2018), https://www.hassan.senate.gov/imo/media/doc/RaoEPALetterFinal.pdf.
[652] FDA, *Technical Information on Development of Fish Consumption Advice - FDA/EPA Advice on What Pregnant Women and Parents Should Know about Eating Fish*,

As noted above, EPA failed to consult with other federal agencies before proposing this rule. EPA also violated its own data access plan, which says EPA "will consider how, when, and whether to apply the EPA policy to research that is subject to public access policies from other agencies" as it recognizes that "duplicative or conflicting requirements might result when research is subject to public access policies from multiple federal agencies".[653] There is no evidence that EPA considered these issues or that EPA followed its own policy to "coordinate with other agencies and the private sector" as it implements new data access policies.[654]

The usual procedures appear to have been set aside for this proposed rule, and EPA has provided no explanation for why shortened review procedures were necessary. It was initially reported that this Proposal was categorized as a "tier 3" measure, subject to the lowest amount of scrutiny in EPA's own internal review process, and developed largely by political appointees with no input from career staff, despite having characteristics of a "tier 1" measure, subject to the highest level of scrutiny.[655] These characteristics include being precedent-setting; controversial; having cross-Agency, cross-media, and inter-agency impacts and controversies; and raising external interest, all of which are present here. Though the agency appears to have now raised it to "tier 1" status, the Proposal that is now available for public comment was subject only to these initial hasty procedures, calling into question its validity.[656]

EPA must withdraw the Proposal and release it only under the full, proper procedures.

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https://www.fda.gov/Food/FoodborneIllnessContaminants/Metals/ucm531136.htm (last accessed Aug. 1, 2018).

[653] EPA, *Plan to Increase Access to Results of EPA-Funded Scientific Research* at 8 (Nov. 29, 2016), https://www.epa.gov/sites/production/files/2016-12/documents/epascientificresearchtransperancyplan.pdf.

[654] *Id.* at 15.

[655] Inside EPA, *EPA Science Plan Skirted Usual Process, Raising Finalization, Legal Doubts* (May 14, 2018), https://insideepa.com/daily-news/epa-science-plan-skirted-usual-process-raising-finalization-legal-doubts.

[656] Inside EPA, *EPA Strengthens Internal Review Of Science Rule As SAB Seeks Scrutiny* (June 1, 2018), https://insideepa.com/daily-news/epa-strengthens-internal-review-science-rule-sab-seeks-scrutiny.

Appendix A. Analysis of Sources Cited to in the Proposal

This appendix provides an analysis of the sources EPA cites in the proposed rule, showing ultimately that EPA has provided no sources or authorities that support or provide a reasoned basis for the proposed rule and that many of the sources raise key implementation concerns that EPA fails at all to address—rendering the proposal arbitrary and capricious.

Footnote 1: See Exec. Order No. 13563, 76 Fed. Reg. 3821 (Jan. 21, 2011). "Our regulatory system must protect public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation. It must be based on the best available science."

Exec. Order No. 13563 requires agencies to utilize the "best available science" in regulatory actions.[657] This requirement is further encoded in numerous statutes and policies that EPA implements. EPA states in the proposed rule that: "The best available science must serve as the foundation of EPA's regulatory actions."[658] However, as the comments raise more thoroughly, by arbitrarily restricting the scientific studies EPA will consider, this proposed rule will *hinder* EPA's use of the best available science and therefore violates the command of Exec. Order No. 13563 and other versions of these requirements.

Furthermore, this executive order requires agencies to "ensure the objectivity of any scientific and technological information and processes used to support the agency's regulatory actions" consistent with the President's Memorandum for the Heads of Executive Departments and Agencies, ''Scientific Integrity'' (March 9, 2009). As the comments note, however, the proposed rule along with the provision allowing the Administrator to grant discretionary exemptions will harm the objectivity of scientific and technological information and processes at EPA by paving the way for politics, rather than objective scientific criteria, to dictate which scientific studies are considered.

Footnote 2: See Memorandum for the Heads of Executive Department[sic] and Agencies on Scientific Integrity (Mar. 9, 2009). "If scientific and technological information is developed and used by the Federal Government, it should ordinarily be made available to the public. To the extent permitted by law, there should be transparency in the preparation, identification, and use of scientific and technological information in policymaking."

EPA claims about the proposal that "[b]y better informing the public, the Agency in[sic] enhancing the public's ability to understand and meaningfully participate in the regulatory process." EPA then cites to the Memorandum for the Heads of Executive Departments and Agencies on Scientific Integrity. [659] Not only does the proposal conflict with this memorandum, but it will make it more difficult for the public to meaningfully participate in the regulatory process.

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[657] Exec. Order No. 13563, 76 Fed. Reg. 3821 (Jan. 21, 2011).
[658] 83 Fed. Reg. at 18,769.
[659] 83 Fed. Reg. at 18,769 n. 2.

The memorandum sets out a number of actions for agencies to take to ensure scientific integrity.[660] Just *one* of these factors involves making scientific and technological information publicly available, notably specifying, "*Except for information that is properly restricted from disclosure* under procedures established in accordance with statute, regulation, Executive Order, or Presidential Memorandum, each agency should make available to the public the scientific or technological *findings or conclusions* considered or relied on in policy decisions."[661] The memorandum thus supports only making scientific findings and conclusions publicly available, not the data underlying those findings and conclusions. Further, it correctly notes that some information is properly restricted from disclosure. It does not say that the inability to disclose such information should prevent it from being considered by agencies. The memorandum thus provides *no* support for the notion that agencies should be barred from relying on studies where the underlying data cannot be disclosed. The memorandum's narrow approach to public disclosure should not be taken to support EPA's proposal but rather counsels against the proposal's mandate that all underlying data be made publicly available.

EPA's proposal fundamentally conflicts with the heart of the memorandum—that "[t]he public must be able to trust the science and scientific process informing public policy decisions."[662] To earn this trust, the memorandum declares: "Political officials should not suppress or alter scientific or technological findings and conclusions."[663] By discarding scientific studies where underlying data cannot be made publicly available, this proposal will result in scientific findings being suppressed. By allowing the Administrator to grant exemptions to this policy based on their discretion with no public record or explanation, the proposal allows for the Administrator to pick and choose based on their preference the science informing the agency's actions, eroding the public's trust in the science informing public policy decisions.

The memorandum provides a number of ways in which agencies can ensure scientific integrity which the proposal does not consider including: hiring candidates for science and technology position based on their "knowledge, credentials, experience, and integrity," having in place appropriate rules and procedures to ensure integrity of the scientific process, establishing scientific processes such as peer review and accurately reflecting scientific and technological information, establishing procedures to identify when scientific integrity may be compromised, including establishing whistleblower protections.[664] EPA does not explain why any of these pathways would not serve as a better means of ensuring scientific integrity.

Footnote 3: EPA has the authority to establish policies governing its reliance on science in the administration of its regulatory functions. Historically, EPA has not consistently observed the policies underlying this proposal, and courts have at times upheld EPA's use

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[660] Memorandum for the Heads of Executive Departments and Agencies on Scientific Integrity (Mar. 9, 2009), 74 Fed. Reg. 10671 (Mar. 11, 2009).
[661] Memorandum for the Heads of Executive Departments and Agencies on Scientific Integrity (Mar. 9, 2009), 74 Fed. Reg. 10671 (Mar. 11, 2009) (emphasis added).
[662] Memorandum for the Heads of Executive Departments and Agencies on Scientific Integrity (Mar. 9, 2009), 74 Fed. Reg. 10671 (Mar. 11, 2009).
[663] Memorandum for the Heads of Executive Departments and Agencies on Scientific Integrity (Mar. 9, 2009), 74 Fed. Reg. 10671 (Mar. 11, 2009).
[664] Memorandum for the Heads of Executive Departments and Agencies on Scientific Integrity (Mar. 9, 2009), 74 Fed. Reg. 10671 (Mar. 11, 2009).

non-public data in support of its regulatory actions. See Coalition of Battery Recyclers Ass'n v. EPA, 604 F.3d 613, 623 (D.C. Cir. 2010); American Trucking Ass'ns v. EPA, 283 F.3d 355, 372 (D.C. Cir. 2002). EPA is proposing to exercise its discretionary authority to establish a policy that would preclude it from using such data in future regulatory actions.

In footnote 3 of the proposal, EPA notes that "courts have at times upheld EPA's use [sic] non-public data in support of its regulatory actions" and cites to *Coalition of Battery Recyclers Ass'n* v. *EPA,* 604 F.3d 613, 623 (D.C. Cir. 2010) and *American Trucking Ass'ns* v. *EPA,* 283 F.3d 355, 372 (D.C. Cir. 2002).[665] These cases indeed held that EPA's prior, long-standing position of relying on scientific studies even when the underlying data could not be made publicly available was reasonable. It is well-established that agencies must acknowledge changes in position and "show that there are good reasons for the new policy."[666] This footnote, the only mention of EPA's previous policy, does not sufficiently acknowledge or explain why EPA is now changing its position.

In *American Trucking Ass'ns* v. *EPA* the Court held that the Clean Air Act did not require EPA to make public underlying data where EPA relied on the study itself and not the raw data underlying the study.[667] The Court stated that such a requirement "would be impractical and unnecessary."[668] They agreed with EPA's then statement that:

> If EPA and other governmental agencies could not rely on published studies without conducting an independent analysis of the enormous volume of raw data underlying them, then much plainly relevant scientific information would become unavailable to EPA for use in setting standards to protect public health and the environment.... Such data are often the property of scientific investigators and are often not readily available because of ... proprietary interests ... or because of [confidentiality] arrangements [with study participants].[669]

In *Coalition of Battery Recyclers Ass'n* v. *EPA*, the Court cited *American Trucking Ass'ns* v. *EPA* and held, again, that EPA was permitted to rely on studies without making the underlying data public.[670] They noted, "raw data often is unavailable due to proprietary interests of a study's scientific investigators or confidentiality agreements with study participants."[671] These court cases thus not only upheld EPA's prior practice as permissible, but went on to agree that EPA's prior practice was preferable and necessary in light of these other policy concerns.

EPA provides no response to this history, saying only: "Historically, EPA has not consistently observed the policies underlying this proposal. . . ."[672] EPA fails explicitly to

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[665] 83 Fed. Reg. at 18, 769.
[666] *FCC v. Fox Television Stations, Inc.* 556 U.S. 502, 515 (2009).
[667] 283 F.3d 355, 372 (D.C. Cir. 2002).
[668] *Id. at 372* (quoting Particulate Matter NAAQS, 62 Fed. Reg. at 38,689.)
[669] *Id.*
[670] 604 F.3d 613, 623 (D.C. Cir. 2010).
[671] *Id.* at 315.
[672] 83 Fed. Reg. at 18, 769.

recognize that this proposal changes its past policy and provides no justification in light of the compelling opposing points that both EPA and the Courts previously recognized as deterring this approach.

Footnote 4: Exec. Order No. 13777, 82 Fed. Reg. 12285 (Mar. 1, 2017). Regulatory reform efforts shall attempt to identify "those regulations that rely in whole or in part on data, information, or methods that are not publicly available or that are insufficiently transparent to meet the standard for reproducibility."

EPA claims that the proposal is consistent with Exec. Order No. 13777.[673] This executive order provides no support for the proposal, and in fact is targeted at eliminating regulations including those that are "unnecessary" and "ineffective," which, as our comments detail, the proposal clearly would be.[674]

This executive order creates a Regulatory Reform Task Force and calls for them to identify for repeal, replacement, or modification regulations that among other criteria

> are inconsistent with the requirements of section 515 of the Treasury and General Government Appropriations Act, 2001 (44 U.S.C. 3516 note), or the guidance issued pursuant to that provision, in particular those regulations that rely in whole or in part on data, information, or methods that are not publicly available or that are insufficiently transparent to meet the standard for reproducibility.[675]

As described in detail in our comments and below, contrary to the inference drawn here in Exec. Order No. 13777, the Data Quality Act and OMB's guidelines issued pursuant to it *do not* require research data and models to be made publicly available for reproducibility purposes in order for agencies to rely on the scientific findings and conclusions produced using that data.

Executive orders cannot override the statutory requirements that EPA use the best available science or the laws governing administrative procedure including the APA. The proposal's "consistency" with this executive order then cannot serve as a legal basis for EPA to adopt an arbitrary and capricious policy that contravenes these best available science requirements reflected in the statutes EPA administers.

Additionally, Exec. Order No. 13777 by its terms requires only the identification of regulations that rely in whole or in part on data not publicly available, it says nothing about precluding agencies from relying on such studies and does not and cannot require agencies to adopt such practices. However, if the proposed rule is to be "consistent" with the executive order then it must also follow section 3(e):

> In performing the evaluation described in subsection (d) of this section, each Regulatory Reform Task Force shall seek input and other assistance, as permitted by law, from entities significantly affected by Federal regulations, including State, local, and tribal

[673] 83 Fed. Reg. at 18, 769.
[674] Exec. Order No. 13777, 82 Fed. Reg. 12285, 12286 (Mar. 1, 2017).
[675] Exec. Order No. 13777, 82 Fed. Reg. 12285, 12286 (Mar. 1, 2017).

governments, small businesses, consumers, non-governmental organizations, and trade associations.[676]

There is no evidence that EPA consulted with the many stakeholders impacted by this policy, including the medical or scientific research communities, which have been largely opposed to this policy.

Footnote 5: Exec. Order No. 13783, 82 Fed. Reg. 16093 (Mar. 31, 2017). "It is also the policy of the United States that necessary and appropriate environmental regulations comply with the law, are of greater benefit than cost, when permissible, achieve environmental improvements for the American people, and are developed through transparent processes that employ the best available peer-reviewed science and economics."

EPA claims the proposal is consistent with Exec. Order No. 13783.[677] However, Exec. Order No. 13783 calls for agencies to consider salient information that the proposal has patently ignored. Exec. Order No. 13783 calls for agencies to consider the costs and benefits "that are based on the best available science and economics" to ensure sound regulatory decision-making.[678] The proposal provides no analysis of the costs and benefits of implementing this new policy, despite there likely being high costs to making research data public with little evidence of significant benefits achieved from this policy alone.

Further, by arbitrarily excluding scientific information that EPA may use in its regulatory analyses, the proposal conflicts with the executive order's command to employ the best available science and economics.[679]

Footnote 6: February 22, 2002 (67 F.R 8453) OMB's Guidelines Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information (2002) https://www.federalregister.gov/documents/2002/02/22/R2-59/guidelines-for- ensuring-and-maximizing-the-quality-objectivity-utility-and-integrity-of-information.

EPA wrongly claims that the proposal is "consistent with. . . the focus on transparency in OMB's *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of Information Disseminated by Federal Agencies*."[680] To say that OMB's Guidelines have a "focus on transparency" that is furthered by EPA's proposal is a gross oversimplification. EPA here appears to suggest that transparency is the highest objective to be achieved, divorced from any consideration of whether transparency hinders or furthers any other goals. The OMB Guidelines, while imposing high standards of quality, objectivity, utility, and integrity of information disseminated by Federal Agencies, recognize the need to implement controls "flexibly, and in a

[676] Exec. Order No. 13777, 82 Fed. Reg. 12285, 12286 (Mar. 1, 2017).
[677] 83 Fed. Reg. at 18,769.
[678] Exec. Order No. 13783, 82 Fed. Reg. 16093, 16095 (Mar. 31, 2017).
[679] Exec. Order No. 13783, 82 Fed. Reg. 16093 (Mar. 31, 2017).
[680] 83 Fed. Reg. at 18,769-70.

manner appropriate to the nature. . . of the information to be disseminated."[681] They suggest thinking about transparency strategically to further the aims of good government, unlike the proposal, which conflates transparency and quality without consideration of other factors.

As part of ensuring "objectivity" of information these guidelines encourage agencies which disseminate influential scientific, financial, or statistical information, "to include a high degree of transparency about data and methods to facilitate the reproducibility of such information by qualified third parties." [682] However, they emphasize the need to treat certain data differently, due to privacy and confidentiality concerns.[683] While they recommend agencies "identify the sources of the disseminated information" they note that this is "to the extent possible, consistent with confidentiality protections."[684] Importantly, they take great pains to urge agencies *not* to subject all data to a reproducibility requirement where this could hamper agencies.[685] They require agencies, instead, to consult with "the relevant scientific and technical communities" to identify data that "can practicable [sic] be subjected to a reproducibility requirement, given ethical, feasibility, or confidentiality constraints."[686] There is no indication that EPA consulted with the scientific and technical community, with EPA's own Science Advisory Board raising concerns about the proposal and finding that "[t]his action merits further review by the SAB."[687] The Guidelines make clear:

> Making the data and methods publicly available will assist in determining whether analytic results are reproducible. However, the objectivity standard does not override other compelling interests such as privacy, trade secrets, intellectual property, and other confidentiality protections.[688]

In direct conflict with the reasoning underlying EPA's proposal, the Guidelines specifically provide that it is possible to verify the objectivity of information that cannot be made publicly available through other types of "robustness checks."[689] As an example, they point to the Harvard Six Cities Study, where underlying data could not be made publicly available due to confidentiality concerns, but the raw data was released instead to researchers at the Health Effects Institute, bound to the same confidentiality requirements as the original researchers, who were able to replicate its results.[690] In contrast, EPA's proposal would not allow for the consideration of this study.[691]

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[681] *OMB's Guidelines Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information*, 67 Fed. Reg. 8452, 8453 (Feb. 22, 2002).
[682] 67 Fed. Reg. 8452, 8460.
[683] *Id.*
[684] 67 Fed. Reg. 8452, 8459.
[685] 67 Fed. Reg. 8452, 8460 ("With regard to original and supporting data related thereto, agency guidelines shall not require that all disseminated data be subjected to a reproducibility requirement.")
[686] *Id.*
[687] Memorandum from SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science (May 12, 2018).
[688] 67 Fed. Reg. 8452, 8460.
[689] *Id.*
[690] 67 Fed. Reg. 8452, 8456.
[691] 83 Fed. Reg. at 18769 n. 3 (citing to a case challenging EPA's reliance on this study and saying the rule "would preclude it from using such data in future regulatory actions.")

The guidelines also recommend agencies recognize that information quality comes at a cost, and that agencies should weigh the costs and benefits, which EPA has not done in the proposal.[692]

Thus, the proposal completely turns away from OMB's guidelines where OMB "urges caution in the treatment of original and supporting data because it may often be impractical or even impermissible or unethical to apply the reproducibility standard to such data." [693] As the comments discuss further, the proposal rule thus unlawfully conflicts with this flexible approach that prioritizes agencies' ability to use science as set out by OMB under the Information Quality Act.

Footnote 7: Memorandum for the Heads of Executive Departments and Agencies on Open Data Policy—Managing Information as an Asset (https://project-open-data.cio.gov/policy-memo/). "Specifically, this Memorandum requires agencies to collect or create information in a way that supports downstream information processing and dissemination activities. This includes using machine-readable and open formats, data standards, and common core and extensible metadata for all new information creation and collection efforts. It also includes agencies ensuring information stewardship through the use of open licenses and review of information for privacy, confidentiality, security, or other restrictions to release."

EPA claims the proposal is consistent with OMB's memorandum on Open Data Policy.[694] This is incorrect, however, as the memorandum supports downstream information processing and dissemination—not through complete public disclosure without regard to privacy or security—but through instituting a framework of data collection, formatting, and storage that allows for public dissemination, *if possible*.[695] Recognizing that not all data can be publicly disclosed, and that such data is still useful, the memorandum declares: "Whether or not particular information can be made public, agencies can apply this framework to all information resources to promote efficiency and produce value."[696]

The proposal is thus inconsistent with the memorandum, which stresses the importance of information stewardship and "review of information for privacy, confidentiality, security, or other restrictions to release."[697] When information cannot be released, the memorandum does not suggest agencies ignore the information or not rely on it for regulatory purposes. It focuses on prescribing agency practices to maximize the downstream usability of data that *can* be made publicly available, including through "using machine-readable and open formats, data standards, and common core and extensible metadata for all new information creation and collection efforts"[698] as well as "building or modernizing information systems in a way that maximizes interoperability and information accessibility, maintains internal and external data asset

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[692] 67 Fed. Reg. 8452, 8452-53.
[693] 67 Fed. Reg. 8452, 8456.
[694] 83 Fed. Reg. at 18,769-70.
[695] Memorandum for the Heads of Executive Departments and Agencies on Open Data Policy—Managing Information as an Asset, M-13-13 (May 9, 2013).
[696] *Id.* at 1.
[697] *Id.* at 2.
[698] *Id.* at 1-2.

inventories, enhances information safeguards, and clarifies information management responsibilities."[699] Thus, while the memorandum centers on how agencies can marginally increase the utility of information they possess for use by the public, the proposal turns this on its head by advocating for discard of otherwise high quality scientific information if the data underlying such information cannot be made publicly available.

OMB stresses that to achieve "open data," agencies should adopt a presumption in favor of openness that is importantly limited by countervailing privacy, confidentiality, security, or other valid restrictions.[700] Thus, agencies are expected to "exercise judgment before publicly distributing data residing in an existing system by weighing the value of openness against the cost of making those data public."[701] The proposal does not at all weigh the costs, to the agency or to the public, of requiring all underlying data to be made publicly available.

While requiring agencies to adopt measures to strengthen privacy protections and data security, the memorandum recognizes serious limitation to data disclosure that EPA completely fails to consider. For example, the memorandum mandates that agencies take into consideration the "mosaic effect,"[702] which EPA does not at all acknowledge—all while making superficial and unsupported statements about how privacy concerns can be easily addressed.[703] The memorandum recognizes and stresses the challenge of responding to this threat, which requires undertaking a "risk-based analysis, often utilizing statistical methods whose parameters can change over time, depending on the nature of the information, the availability of other information, and the technology in place that could facilitate the process of identification."[704] OMB importantly notes this analysis "may affect the amount, type, form, and detail of data released by agencies."[705] Because it ignores these concerns, EPA's proposal is arbitrary and capricious.

Footnote 8: Plan to Increase Access to Results of EPA-Funded Scientific Research; EPA Open Government Plan 4.0; Open Data Implementation Plan; EPA's Scientific Integrity

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[699] *Id.* at 2.
[700] *Id.* at 5.
[701] *Id.* at 6.
[702] OMB explains: "The mosaic effect occurs when the information in an individual dataset, in isolation, may not pose a risk of identifying an individual (or threatening some other important interest such as security), but when combined with other available information, could pose such risk. Before disclosing potential PIT or other potentially sensitive information, agencies must consider other publicly available data–in any medium and from any source--to determine whether some combination of existing data and the data intended to be' publicly released could allow for the identification of an individual or pose another security concern." Memorandum for the Heads of Executive Departments and Agencies on Open Data Policy—Managing Information as an Asset, M-13-13 at 4-5 (May 9, 2013).
[703] Memorandum for the Heads of Executive Departments and Agencies on Open Data Policy—Managing Information as an Asset, M-13-13 at 9-10 (May 9, 2013). *See, e.g.*, 83 Fed. Reg. at 18,770 ("EPA believes that concerns about access to confidential or private information can, in many cases, be addressed. . . .")
[704] Memorandum for the Heads of Executive Departments and Agencies on Open Data Policy—Managing Information as an Asset, M-13-13 at 9-10 (May 9, 2013).
[705] Memorandum for the Heads of Executive Departments and Agencies on Open Data Policy—Managing Information as an Asset, M-13-13 at 10 (May 9, 2013).

Policy; Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency.

Rather than acknowledge the drastic change in EPA policy this proposal would implement, EPA contrarily claims that the proposal simply "builds upon prior EPA actions."[706] None of the sources EPA cites here call into question the validity of scientific research for which underlying data and models cannot be made public. Indeed, they consistently recognize the legitimate limitation on data disclosure while also acknowledging the need for the agency to rely on information for which underlying data may not be released without compromising important privacy and confidentially concerns.

I. Plan to Increase Access to Results of EPA-Funded Scientific Research, https://www.epa.gov/sites/production/files/2016-12/documents/epascientificresearchtransperancyplan.pdf

Contrary to EPA's claim that the proposal "builds upon" prior EPA policy, it is actually a radical shift away from the view EPA takes in its *Plan to Increase Access to Results of EPA-Funded Scientific Research*, which notes even though "some research data cannot be made fully available to the public but instead may need to be made available in more limited ways," this availability "does not affect the validity of the scientific conclusions from peer-reviewed research publications."[707] The *Plan to Increase Access to Results of EPA-Funded Scientific Research* thus dictates the view EPA has consistently espoused in the past, that it may make data available when it can without compromising other critical values, but that it will not exclude information from its consideration when it cannot. Yet EPA denies, rather than acknowledging and explaining, its new decision to reverse its past stance.

The *Plan* requires EPA to make publications resulting from EPA-funded research publicly accessible on NIH's PubMed Central (PMC).[708] It aims to "maximize access, by the general public and without charge, to digitally formatted data resulting from EPA funded research, *while protecting confidentiality and personal privacy, recognizing proprietary interests, business confidential information and intellectual property rights, and preserving the balance between the relative benefits and costs of long-term preservation and access.*"[709] It recognizes important exceptions for when "the research data cannot be released due to one or more constraints, such as requirements to protect confidentiality, personal privacy, proprietary interest, or property rights."[710] It specifically declares: "The validity of scientific conclusions drawn from research publications or their associated research data, or EPA's ability to consider those conclusions and data in its actions, does not depend on compliance with this Plan."[711]

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[706] 83 Fed. Reg. at 18,770.
[707] EPA, *Plan to Increase Access to Results of EPA-Funded Scientific Research* 4-5 (Nov. 29, 2016), https://www.epa.gov/sites/production/files/2016-12/documents/epascientificresearchtransperancyplan.pdf
[708] *Id.* at 8.
[709] *Id.* at 11 (emphasis added).
[710] *Id.*
[711] *Id.* at 6.

The *Plan* acknowledges making more limited releases of data "e.g., establishing data use agreements with researchers that respect necessary protections," that fall short of full public disclosure.[712] Unlike the proposal, which fails to account for the costs of implementation, the plan also acknowledges the need to "balance between the value of providing long-term access and its associated costs."[713]

The *Plan* thus further enshrines the view that this rule is unnecessary—where EPA has access to data and can release it without compromising other interests, it already does so. It further supports the notion that this type of disclosure is not necessary, and will not help, to ensure EPA's reliance on valid scientific conclusion. EPA must fully explain its decision to deviate from this prior-held stance.

II. EPA Open Government Plan 4.0, https://www.epa.gov/sites/production/files/2016-09/documents/2016epaopengovplan4_0draft091516update1.pdf

EPA's *Open Government Plan 4.0* also acknowledges that not all data is releasable to the public, even as it aims to "increase publicly accessible EPA data to support citizens' participation in government and promote transparency and accountability of Agency operations."[714] EPA states in the *Plan*: "By providing *releasable* information in open and machine-readable formats, EPA enables the public and other organizations to better leverage the rich wealth of information available."[715] Further, in the *Plan* EPA notes the stringent requirements it has in place on the "collection, access, use, dissemination, and storage of personally identifiable information (PII) and Privacy Act information to prevent unwarranted invasions of personal privacy."[716]

Rather than suggesting that EPA release underlying data to the public in order to rely on scientific information, the *Plan* only speaks to utilizing a careful approach—with due regard for privacy and limitations to data release—to making EPA data more accessible to the public where possible.

III. Open Data Implementation Plan, https://www.epa.gov/sites/production/files/2015-05/documents/opendatapolicyimplementationplan_030415_finalb.pdf

EPA's own Open Data Policy, which implements the requirements of White House "Open Data Policy – Managing Information as an Asset" Memorandum M-13-13, notes that it is important to develop "policies and processes to ensure that only appropriate data are released to

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[712] *Id.* at 4.
[713] *Id.*
[714] EPA, *Open Government Plan 4.0* 4 (Sep. 2016), https://www.epa.gov/sites/production/files/2016-09/documents/2016epaopengovplan4_0draft091516update1.pdf.
[715] EPA, *Open Government Plan 4.0* 4 (Sep. 2016), https://www.epa.gov/sites/production/files/2016-09/documents/2016epaopengovplan4_0draft091516update1.pdf (emphasis added).
[716] EPA, *Open Government Plan 4.0* 23 (Sep. 2016), https://www.epa.gov/sites/production/files/2016-09/documents/2016epaopengovplan4_0draft091516update1.pdf.

the public and made available online."[717] To do so, EPA uses different "access levels" for different data sets, (public, restricted public, and non-public) and notes that it may not be able to publicize data due to "law, regulation or policy, which address privacy, confidentiality, security or other valid restrictions."[718]

Thus, while the Open Data Policy applies a multi-level, nuanced approach to data disclosure, the Proposal completely does away with this by applying a blanket requirement to make all underlying data and models publicly available. The Open Data Policy this conflicts with, rather than supports, the Proposal.

IV. EPA's Scientific Integrity Policy, https://www.epa.gov/sites/production/files/2014-02/documents/scientific_integrity_policy_2012.pdf

Contrary to EPA's claim, the Proposal turns away from EPA's Scientific Integrity Policy, which stresses "a firm commitment to evidence," endorses use of "the best available science" and "[r]equire[s] reviews. . . regarding the content of a scientific product to be based only on scientific quality considerations."[719] The Proposal, on the other hand, inhibits use of sound scientific information and evidence by arbitrarily excluding science from EPA's consideration for reasons unrelated to its quality.[720]

While the policy "[r]ecognizes the value of independent validation of scientific methods"[721] and facilitating "the free flow of scientific information" by making information available "including access to data and non-proprietary models underlying Agency policy decisions,"[722] this is a flexible standard and an ideal to aspire to, not to take priority over other competing interests—such as use of the best available science. This measure is meant to "facilitate[] the free flow of scientific information" and "expand and promote access to scientific information."[723] The Proposal, however, limits the free flow of scientific information and restricts access to scientific information by restricting EPA's consideration of scientific studies.

As discussed in our comments, this Administration has blatantly violated key aspects of the policy by silencing scientists and the limiting the dissemination of scientific information, directly undoing "EPA's longstanding commitment to the timely and unfiltered dissemination of its scientific information – uncompromised by political or other interference" and goal to communicate scientific findings openly and actively to the public.[724] The Scientific Integrity Policy is meant to uphold scientific ideals—and prevent arbitrary, politicized decisions about which science to utilize—and the Proposal is thus in strong conflict with it.

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[717] EPA, *Open Data Policy Implementation Plan* 4 (Feb. 2015), https://www.epa.gov/sites/production/files/2015-05/documents/opendatapolicyimplementationplan_030415_finalb.pdf.
[718] EPA, *Open Data Policy Implementation Plan* 4 (Feb. 2015), https://www.epa.gov/sites/production/files/2015-05/documents/opendatapolicyimplementationplan_030415_finalb.pdf.
[719] EPA, *Scientific Integrity Policy* 4, https://www.epa.gov/sites/production/files/2014-02/documents/scientific_integrity_policy_2012.pdf.
[720] *Id.* at 3-4.
[721] *Id.* at 4.
[722] *Id.*
[723] *Id.*
[724] *Id.* at 5.

V. Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency, https://www.epa.gov/quality/guidelines-ensuring-and-maximizing-quality-objectivity-utility-and-integrity-information

EPA's Proposal also does not "build upon" its *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency*. The *Guidelines* note that it may not be possible for underlying data and models to be subject to same degree of disclosure as analytic results, and highlight other methods of ensuring the quality of scientific research where disclosure is not possible.

The *Guidelines* start by noting, "[t]he mission of the EPA is to protect human health and safeguard the natural environment upon which life depends" and "[t]he collection, use, and dissemination of information of known and appropriate quality are integral to ensuring that EPA achieves its mission."[725] They thus highlight that the controls on data quality exist to allow EPA to meet its mission—unlike the Proposal, which makes no mention of EPA's mission or how the Proposal would further that mission. Because the Proposal restricts EPA's ability to rely on the best available science, it obscures EPA in achieving its mission to set safeguards that are protective of human health and the environment, and thus such a statement could not truthfully be made.

While the *Guidelines* seek to maximize the quality of influential information by facilitating the reproducibility of the information—they note:

> In addition, if access to data and methods cannot occur due to compelling interests such as privacy, trade secrets, intellectual property, and other confidentiality protections, EPA should, to the extent practicable, apply especially rigorous robustness checks to analytic results and carefully document all checks that were undertaken. Original and supporting data may not be subject to the high and specific degree of transparency provided for analytic results; however, EPA should apply, to the extent practicable, relevant Agency policies and procedures to achieve reproducibility, given ethical, feasibility, and confidentiality constraints.[726]

EPA's *Guidelines* detail EPA's long-standing position, that it may validate research studies even when data cannot be made publicly available—unlike the Proposal, which apparently assumes disclosure of underlying data and models is necessary to ensure scientific validity. The *Guidelines* discuss existing programs, such as EPA's Quality System and EPA's Peer Review

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[725] EPA, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency* 5 (Oct. 2002), https://www.epa.gov/quality/guidelines-ensuring-and-maximizing-quality-objectivity-utility-and-integrity-information.

[726] *Id.* at 21.

Policy[727] that are in place to assure the high quality of EPA information disseminates. EPA does not explain in the Proposal why these other checks are now insufficient.

Footnote 9: For example, see related policies from the National Science Foundation, National Institute of Science and Technology, the National Institutes of Health; and the US Census Bureau, which provides secure access to data from several agencies in an environment that protects against unauthorized disclosure (https://www.census.gov/fsrdc).

EPA purports that the Proposal builds upon "the experience of other federal agencies in this space" but the citations reveal that is simply not the case.[728] To support this statement, EPA provides only a hyperlink to a U.S. Census Bureau website along with vague references to entire executive branch agencies, with no explanation or discussion of which of their policies EPA believes the Proposal is building upon. Without a more specific citation, it is impossible to know which policies EPA is referencing or to respond to them meaningfully.

EPA cites to the U.S. Census Bureau's Federal Statistical Research Data Centers as an example of use of secure facilities that allow the Census Bureau to provide controlled access to authorized researchers to use restricted-use microdata for statistical purposes only. In order to gain access, researchers must obtain Census Bureau Special Sworn Status by passing a moderate risk background check and swearing to protect respondent confidentiality for life. While this "solution" meets the U.S. Census Bureau's needs by allowing access to confidential information only to researchers whose proposals meet certain criteria, who go through a vetting process, and who agree to protect the information, this is done at a cost—which EPA has not accounted for—and would not satisfy EPA's requirement to make data and models "publicly available." Thus, this example provides no support for the Proposal.

Footnote 10: These include policies and recommendations from: the Administrative Conference of the United States' Science in the Administrative Process Project; National Academies' reports on Improving Access to and Confidentiality of Research Data, Expanding Access to Research Data, and Access to Research Data in the 21st Century; the Health Effects Institute; Center for Open Science; members of the Risk Assessment Specialty Section of the Society of Toxicology, the Dose Response Section of the Society for Risk Analysis, and the International Society for Regulatory Toxicology and Pharmacology; and the Bipartisan Policy Center's Science for Policy Project.

In footnote 10, EPA lists a number of organizations whose recommendations and policies the Proposal allegedly took into consideration. In fact, since the Proposal was published, many of these organizations have issued statements opposing the Proposal and contesting EPA's claim that their policies and recommendations endorse the Proposal. In this footnote, EPA provided no hyperlinks or specific citations for which recommendations and policies it was referencing, making it impossible to understand why EPA believed these organizations supported the Proposal or to respond to them.

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[727] *Id.* at 10-13.
[728] 83 Fed. Reg. at 18,770.

I. The Administrative Conference of the United States' Science in the Administrative Process Project

EPA cites to the Administrative Conference of the United States' Science in the Administrative Process Project—*Recommendation 2013-3: Science in the Administrative Process*. Wendy Wagner, sole author of ACUS's final report *Science in Regulation: A Study of Agency Decisionmaking Approaches* and who served on the panel that produced the recommendations strongly opposed the notion that the Proposal builds upon these recommendations, saying: "They don't adopt any of our recommendations, and they go in a direction that's completely opposite, completely different. . . . They don't adopt any of the recommendations of *any* of the sources they cite. I'm not sure why they cited them."[729]

While ACUS recommends agencies increase transparency of how they rely on scientific information and strive to make data underlying scientific information publicly available, nowhere do they suggest that agencies should not consider or rely on studies where underlying data and models cannot be made publicly available, or that these circumstances make scientific information less valid. They instead suggest that information be made publicly available for assessment and reproducibility purposes "[c]onsistent with the limitations in the Information Quality Act (IQA) guidelines issued by the Office of Management and Budget and its own IQA guidelines."[730] They acknowledge valid limitations such as legal protections for privacy, trade secrets, and confidential business information.[731] Thus, they recommend data be made public only "[t]o the extent practicable and permitted by law and applicable policies."[732] Unlike the Proposal, the recommendation acknowledges that agencies may still use information where underlying data cannot be publicly disclosed, and suggest agencies "note that fact and explain why they used the results if they chose to do so."[733] It thus provides a much more nuanced policy recommendation than that outlined in the Proposal—which suggests EPA either find a way to make underlying data and models public, despite the numerous potential obstacles and concerns in doing so, or completely disregard the research study.

II. National Academies Improving Access to and Confidentiality of Research Data

Rather than containing any particular recommendations or policy proposals, this report discusses a number of issues pertaining to data disclosure and privacy protection, the tradeoffs "between increasing data access on the one hand and improving data security and confidentiality

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[729] Robinson Meyer, *Scott Pruitt's New Rule Could Completely Transform the EPA*, The Atlantic (Apr. 25, 2018), https://www.theatlantic.com/science/archive/2018/04/how-the-epas-new-secret-science-rule/558878/.

[730] *Administrative Conference Recommendation 2013-3: Science in the Administrative Process,* 78 Fed. Reg. 41,352, 41,358 (July 10, 2013).

[731] *Administrative Conference Recommendation 2013-3: Science in the Administrative Process,* 78 Fed. Reg. 41,352, 41,356 (July 10, 2013).

[732] *Administrative Conference Recommendation 2013-3: Science in the Administrative Process,* 78 Fed. Reg. 41,352, 41,357 (July 10, 2013).

[733] *Administrative Conference Recommendation 2013-3: Science in the Administrative Process,* 78 Fed. Reg. 41,352, 41,358 (July 10, 2013).

on the other,"[734] and "alternative approaches to limiting disclosure risk while facilitating data access the benefits and limitation of various approaches to these issues."[735] Thus, rather than calling on agencies to rely only on scientific studies where the underlying data and models are made public, the report in fact discusses challenges and obstacles to achieving greater data disclosure, for which the Proposal provides no substantive or meaningful explanation.

The report discusses why exercising caution with respect to disclosing confidential personal information is so important, because if such information is exposed it could lead to

> being arrested for a crime, being denied eligibility for welfare or Medicaid, being charged with tax evasion, losing a job or an election, failing to qualify for a mortgage, or having trouble getting into college. Disclosure of a history of alcoholism, mental illness, venereal disease, or illegitimacy can result in embarrassment and loss of reputation. Less directly, research results based on personal data can cause harm by affecting perceptions about a group to which a person belongs.[736]

The report reveals very legitimate reasons why researchers and study participants would be reluctant to allow underlying data to be made publicly available—and these reasons in no way compromise the validity of the scientific conclusions based upon this data.

The report also discusses the nuances of selecting methods to protect privacy while making underlying data publicly available. For example, while EPA casually makes claims that controlled access is an example of a solution in place across federal agencies[737]—this report points out the drawbacks of such an approach:

> The use of restricted access arrangements, which has been deemed necessary to provide adequate protection for confidential information about individuals and businesses, results in increased costs to conduct research. Custodians of the data files need additional resources to process applications, operate inspection systems, staff research data centers, and inspect outputs to ensure that disclosure does not occur. Researchers require resources to prepare applications for access, to provide appropriate physical security for the data, or to visit a secure site.[738]

The report also discusses the difficulty of funding such centers—noting that while the costs are currently covered by a combination of federal agency budgets and user fees, including grants from the National Science Foundation and National Institute on Aging, federal funding may no longer be able to support such efforts.[739] EPA's cursory mention to use of restricted access facilities as a potential solution to the concerns implicated by the Proposal fail to mention or address any of these challenges.

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[734] The National Academies, *Improving Access to and Confidentiality of Research Data: Report of a Workshop*, National Academies Press 2-3 (2000).
[735] *Id.* at 3.
[736] *Id.* at 19.
[737] 83 Fed. Reg. at 18,771.
[738] *Id.* at 48.
[739] *Id.*

III. National Academies Expanding Access to Research Data: Reconciling Risks and Opportunities

EPA's Proposal in no way takes into consideration the recommendations of the National Academies report *Expanding Access to Research Data: Reconciling Risks and Opportunities*. This report considers competing approaches to increase use of research data while protecting confidentiality, and concludes that "no one way is optimal for all data users or all purposes" and, importantly, that "the nation's statistical and research agencies must provide both unrestricted access to anonymized public-use files and restricted access to detailed, individually identifiable confidential data for researchers under carefully specified conditions."[740] In other words, the report finds that making data publicly available without restriction while respecting confidentiality concerns is not currently feasible or compatible with the missions of federal agencies.

Furthermore, the report mainly concerns itself with how agencies might increase access to data in their control and possession to allow for more research in social issues and provide a better basis for more informed policy decisions—it does not discuss whether federal agencies should make data publicly available in order to allow for independent validation of scientific research they rely on for regulatory purposes and thus cannot be a basis for the Proposal.[741] While the report discusses that one of the benefits of data sharing is that it allows for "verification, refutation, or refinement of original results," nowhere does the report suggest that agencies should rely only on research studies that make data publicly available or that such verification is necessary to validate a research study.[742] Indeed, it details a discussion on this topic that presents competing views on requirements to make research data available to the public to allow for replication. John Bailar raised concerns that researchers would be deterred from doing certain kinds of work if they feared it would be subject to "hostile scrutiny" and that competitors could seize data for their interests.[743] Others disagreed with this position.[744] However, EPA failed to engage any of these considerations or at all justify its decision to implement a policy that could have severe negative implications. None of the researchers stated agencies should disregard the study if underlying data could not be made public.

The "recommendations" made by the report do not endorse EPA's proposal. The report provides 15 recommendations in Chapter 5.[745] Recommendations 1-4 concern documentation and data access and call on agencies to better document how the data they make available is used; to use a variety of modes to provide access to data they produce or fund using a combination of restricted access to confidential data and unrestricted access to appropriately altered public-use data; to support research to guide more efficient allocation of resources among different data access modes; and to involve users in planning modes of access to their data.[746]

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[740] The National Academies, *Expanding Access to Research Data: Reconciling Risks and Opportunities*, National Academies Press 2 (2005).
[741] *Id.* at 7.
[742] *Id.* at 39.
[743] *Id.* at 105-06.
[744] *See id.* at 107.
[745] *Id.* at 63.
[746] *Id.* at 66-69.

In this Proposal, EPA does nothing to better document use of data that it makes public, has only called for a requirement to make research data and models "publicly available" rather than recognizing that a variety of modes and levels of access may be necessary, and does nothing to support more research into methods of making data more widely available without compromising confidentiality—indeed blithely assuming that such means are already available and sufficient—and also has not indicated that there has been any widespread call for EPA to make such data available or pointed to any comments of users of this data in this process.

Recommendations 5-8 concern public use data and call on agencies to support research on techniques to provide useful innovative public-use data that minimizes the risk of disclosure; streamlined procedures to allow researchers access to public-use microdata through existing and new data archives; a warning on all public-use data that they are provided for statistical purposes only and that any attempt to identify an individual is a violation, and requiring users to attest to having read the warning; and restricting access to public-use data to those who agree to abide by confidentiality protections, subject to meaningful penalties.[747]

EPA's proposal once again ignores these recommendations that call for greater research and a measured approach to making data more widely available. The Proposal provides no ideas or methods or support for research that would help strengthen confidentiality protections while making data more available.

Recommendations 9-13 concern research data centers, remote access, and licensing agreements and call on the Census Bureau to (1) broaden the interpretation of the criteria for assessing the benefits of access to data; (2) maintain the continuous review cycle; and (3) take account of prior scientific review of research proposals by established peer review processes when awarding access to research data centers; for more research on cost effective means of providing secure access to confidential data by remote access; increasing use of licensing agreements for access to confidential data; working with data users to develop flexible, consistent standards for licensing agreements and implementation procedures for access to confidential data; and including auditing procedures and legal penalties in licensing agreements for willful misuse of confidential data.[748]

EPA's proposal does not increase any research into use of remote data centers or licensing agreements, simply making passing references to these modes as potential solutions with no discussion or explanation—and ignoring the recommendations here suggesting that more work is needed to realize their potential.

Recommendations 14-15 concern maintaining the public's trust and call on agencies to give certain basic information about confidentiality and data access to everyone asked to participate in statistical surveys; and to support continuing research on the views of data providers and the public about research benefits and risks.[749]

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[747] *Id.* at 69-74.
[748] *Id.* at 74-80.
[749] *Id.* at 80-81.

EPA's proposal does not involve anything that increases the public knowledge about confidentiality protections or their views on research benefits and risks.

Recommendations 16-19 concern training, monitoring, and education to complement other protections on data. They call on data collection agencies to provide employees with continually updated written guidelines on confidentiality protection and training in confidentiality practices and data management and to institute procedures for monitoring violations of confidentiality protections practices and confidentiality breaches. They also call on educational and professional organizations to provide training in ethical issues for all those involved in the design, collection, distribution, and use of data obtained under pledges of confidentiality and for the development of strong codes of ethical conduct that reflect the need to protection confidentiality.[750]

EPA's proposal also contains no provisions on increasing training, monitoring, or education, within the agency or among researchers to allow for more careful handling of confidential data.

Thus, EPA's Proposal completely ignores the careful research and thinking the National Academies and researchers have done on what is needed from federal agencies in order to make data more publicly available, and how to do so in a responsible manner. It does not implement any of the recommendations in the report, and in no way builds upon this work.

IV. National Academies Access to Research Data in the 21st Century: An Ongoing Dialogue Among Interested Parties: Report of Workshop

EPA cites to the National Academies' *Access to Research Data in the 21st Century: An Ongoing Dialogue Among Interested Parties: Report of Workshop* as one for which it took into consideration "policies or recommendations," despite the fact that this report comes with the explicit limitation that:

> The goal of the workshop was not to reach conclusions or recommendations; nor could it address other pressing issues beyond the regulatory process, such as protection of intellectual property, the influence of broader access on scientific competition, the potential for increased administrative burdens and changes in the research process, and the challenge of providing data access in an increasingly electronic world.[751]

Thus, this report stresses the many unanswered, challenging policy questions that must be addressed as agencies contemplate how to make data publicly available. These are the questions EPA should have addressed in its Proposal, but did not.

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[750] *Id.* at 81-84.

[751] Science, Technology, and Law Panel; Policy and Global Affairs; National Research Council, *Access to Research Data in the 21st Century: An Ongoing Dialogue Among Interested Parties: Report of Workshop*, The National Academies Press ix (2002).

The Report offers a look into the scientific review process that also calls into question the underlying assumption in EPA's proposal—that making data publicly available is necessary to ensure the validity of a scientific finding. The report notes that scientific claims "are not 'binary'" they instead "fall in the category of being uncertain to various degrees."[752] The reliability of a particular scientific finding can be assessed using various mechanisms, starting with an examination of the strength of the design, methods, and statistical results.[753] Then "one asks whether there is consistency within the data (pertaining to mechanisms of effect or related outcomes) and with other studies and scientific theories."[754] Finally, "the robustness of the findings is evaluated through the use of different analytical approaches."[755]

The report describes how studies may be validated through a range of approaches.[756] While it notes that in some cases it is possible to exactly replicate the original study, this is not always the case, especially in large epidemiological studies where "repeating a study is seldom either possible or desirable."[757] Then "replication" can take a variety of forms, not all of which require access to underlying data, including:

- Additional analyses done on the data set by the original or collaborating Investigators;
- New results generated from older data sets;
- New studies addressing the same hypothesis;
- Independent analysis of the same data set by different people;
- Monitoring of the results of actions taken on the basis of the findings.[758]

Another form of replication the report describes is

> meta-analysis, which is a systematic strategy for comprehensively describing and summarizing a body of research evidence from two or more studies. The goal is to produce a quantitative synthesis of the evidence presented in multiple studies that relate to a research question. In a typical meta-analysis, all the data used have been published in the public domain and are easy to inspect and analyze.[759]

The report specifically mentions the Harvard Six Cities Study as an example of a study where data could not be made publicly available, but which was verified to allow the agency to justifiably rely on it to set important air standards.[760] Thus, unlike the Proposal the report acknowledges the many different pathways that exist to for researchers to assess other studies, and does not suggest that allowing the general public access to underlying data and models is necessary.

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[752] *Id.* at 5.
[753] *Id.* at 7.
[754] *Id.*
[755] *Id.*
[756] *Id.*
[757] *Id.*
[758] *Id.* at 7-8.
[759] *Id.* at 8.
[760] *Id.* at 8-12.

One of the panels of the workshop discussed the Shelby Amendment, and public access to data underlying agency regulation. A bench scientist expressed concerns that, though the idea of sharing data was a good idea, because any person could request information for any reason, this mechanism could be used to harass scientists whose work was found objectionable.[761] A representative of NIH similarly stated that while sharing data with other researchers was good scientific practice, allowing for indiscriminate public access to data serves "little purpose for those without the skills to reanalyze it."[762] Additionally, access through FOIA does not allow for limitations to be put on the use of the data, which is typically available in other data-sharing modes.[763] A representative from EPA raised issues including:

> The Shelby Amendment. . .raises several questions for the EPA about rule making as a legal and deliberative process. At what point should the agency disclose what type of regulation is going to be considered or issued? The timing of the release can influence its reception. Should the agency use contracts to support the research needed for regulations? Contracting, as opposed to grants that support more flexible work, might narrow the type of information the agency receives and could possibly limit the scope of the science underlying the regulation.[764]

These questions and concerns are highly relevant to the Proposal as well, yet EPA provides no indication that it has given them any consideration.

Finally, a representative from NRDC pointed to other mechanisms that are already in place to ensure agencies rely on high quality data. For example, under the Administrative Procedure Act, agencies must respond to any comments that raise questions about a scientific studies design, performance, or conclusion.[765] Courts can determine whether an agency was reasonable in its decision to refuse to accept the findings of a study because it could not access underlying data or refuses a request from a study participant.[766] EPA does not explain why these existing mechanisms are not sufficient to ensure the integrity of the science it relies on.

V. The Health Effects Institute

In the original federal register notice, EPA provided no specificity as to which Health Effects policy EPA was referring to or why it supported the Proposal. Such a vague and unspecified reference does not meet the notice requirements of the APA and other statutes, and makes it impossible to respond.

VI. Center for Open Science

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[761] *Id.* at 14.
[762] *Id.* at 15.
[763] *Id.*
[764] *Id.* at 16.
[765] *Id.* at 17.
[766] *Id.*

In the original federal register notice, EPA provided no specificity as to which Center for Open Science policy EPA was referring to or why it supported the Proposal. Such a vague and unspecified reference does not meet the notice requirements of the APA and other statutes, and makes it impossible to respond.

VII. Members of the Risk Assessment Specialty Section of the Society of Toxicology, the Dose Response Section of the Society for Risk Analysis, and the International Society for Regulatory Toxicology and Pharmacology

In the original federal register notice, EPA provided no specificity as to which policy of the Members of the Risk Assessment Specialty Section of the Society of Toxicology, the Dose Response Section of the Society for Risk Analysis, and the International Society for Regulatory Toxicology and Pharmacology EPA was referring to or why it supported the Proposal. Such a vague and unspecified reference does not meet the notice requirements of the APA and other statutes, and makes it impossible to respond.

VIII. Bipartisan Policy Center's Science for Policy Project

In the original federal register notice, EPA provided no specificity as to which Bipartisan Policy Center's Science for Policy Project policy EPA was referring to or why it supported the Proposal. Such a vague and unspecified reference does not meet the notice requirements of the APA and other statutes, and makes it impossible to respond.

Footnote 11: For example, see related policies from the Proceedings of the National Academy of Sciences, PLOS ONE, Science, and Nature

EPA claims that the Proposal takes into consideration policies adopted by scientific journals, but does not specify which "related policies" from these journals.[767] While some of these journals have adopted certain policies encouraging or requiring researchers to share underlying data for the studies they publish, they all allow for exceptions when data cannot be released for compelling reasons, such as confidentiality protections.

Furthermore, the editors of these journals have issued a joint statement opposing the Proposal and noting that their policies do not endorse such an approach by EPA. They note that some data sets cannot be shared publicly, and that there are still other methods available to verify scientific findings. The statement also strongly condemns the notion of excluding scientific information from consideration when underlying data cannot be made publicly available:

> It does not strengthen policies based on scientific evidence to limit the scientific evidence that can inform them; rather, it is paramount that the full suite of relevant science vetted through peer review, which includes ever more rigorous features, inform the landscape of decision making. Excluding relevant studies simply because they do not meet rigid transparency standards will adversely affect decision-making processes.[768]

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[767] 83 Fed. Reg. at 18,770.

[768] Jeremy Berg et. al., *Joint statement on EPA proposed rule and public availability of data*, Science (Apr. 30, 2018), http://science.sciencemag.org/content/early/2018/04/30/science.aau0116.

Thus, EPA cannot claim that the Proposal is in any way supported by the data sharing policies of these scientific journals.

Footnote 12: See: https://www.nature.com/articles/s41562- 016-0021; http://journals.plos.org/plosmedicine/ article?id=10.1371/journal.pmed.0020124; http://science.sciencemag.org/content/343/6168/229.long; https://www.economist.com/news/leaders/21588069-scientific-research-has-changed-world-now-it-needs-change-itself-how-science-goes-wrong.; http://stm.sciencemag.org/content/8/341/341ps12.full.

EPA claims that the Proposal is informed by the policies of scientific journals in response to the "replication crisis."[769] EPA provides no explanation or evidence to support the fact that such a "crisis" is occurring or that EPA's Proposal would do anything to address the crisis. The sources EPA cites for this proposition speak to a concern about scientific studies being reproducible or replicable due to a number of different conditions related to poor scientific practices. While some of the articles speak about making data more available as an ideal to aspire to, none of them support the idea that a research study whose underlying data has not been made publicly available should, for that reason alone, be considered invalid. Further, many of these articles speak to how current scientific norms do not result in underlying data being available, which is a huge barrier to EPA's Proposal that EPA does not at all address.

I. Marcus R. Munafó et. al, *A Manifesto for Reproducible Science*, 1 Nature Human Behavior 1 (2017)

Far from suggesting that agencies rely only on scientific studies if the underlying data is made public, or even that making underlying data public is necessary to ensure validity of scientific conclusions, the article discusses at a high level a number of systemic and cultural challenges to reproducible science. By ignoring the nuances of this article and presenting it without any explanation as support for its Proposal, EPA runs into the problem the article specifically cautions against, warning: "Some solutions may be ineffective or even harmful to the efficiency and reliability of science, even if conceptually they appear sensible."[770]

This article does not endorse the existence of a "replication crisis" and in fact says, "[w]hether 'crisis' is the appropriate term to describe the current state or trajectory of science is debatable."[771] Instead it notes a very different problem than the one EPA appears to target with the Proposal. It points broadly to an issue of there being "substantial room for improvement with regard to research practices to maximize the efficiency of the research community's use of the public's financial investment in research."[772]

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[769] 83 Fed. Reg. at 18,770.
[770] Marcus R. Munafó et. al, *A Manifesto for Reproducible Science*, 1 Nature Human Behavior 1, 7 (2017).
[771] *Id.* at 1.
[772] *Id.* at 1.

This article makes clear that open data requirements are just *one* of many solutions and steps to take towards increasing efficiency of use of resources and robustness of scientific findings—and never suggests that a lack of publicly available underlying data should automatically disqualify a research finding from consideration. It discusses a number of other improvements including protecting against cognitive biases through blinding, improving methodological training, implementing methodological support, encouraging collaboration and team science, promoting study pre-registration, improving quality of reporting, diversifying peer review, and changing incentives to promote efficient and effective research instead of just innovative outcomes.

While the article recognizes transparency as a "scientific ideal"[773] it notes many challenges that currently exist to achieving this ideal, which EPA does not at all address. The article notes, "In reality, science often lacks openness: many published articles are not available to people without a personal or institutional subscription, and most data, materials and code supporting research outcomes are not made accessible, for example, in a public repository."[774] It further finds "substantial barriers to meeting these ideals, including vested financial interests (particularly in scholarly publishing) and few incentives for researchers to pursue open practices." Nowhere does the article suggest that the many scientific studies for which data is not available due to prevailing scientific norms and practices be completely discarded. These challenges suggest that many studies EPA wishes to rely on may not be able to meet the rigid requirements of EPA's proposal severely restricting the science EPA can use, degrading the quality of its decision-making.

Marcus R. Munafó, lead author on this paper, has since published a piece specifically dismissing science policy approaches that overemphasize the importance of replication.[775] It states that the overemphasis on replicability is detrimental to science—that "[i]f a study is skewed and replications recapitulate that approach, findings will be consistently incorrect or biased."[776] Instead, the author suggests that "an essential protection against flawed ideas is triangulation" or "the strategic use of multiple approaches to address one question."[777] This involves looking at a broad base of different scientific studies and does not require underlying data to be made publicly available, not individual studies based on whether or not they can be replicated.[778] By excluding scientific studies from EPA's consideration, the Proposal overemphasizes the value of replication to the detriment of being able to evaluate a study in the context of many other studies examining the same issue through a variety of methods. The Proposal may well lead to reliance on less robust science and is thus arbitrary.

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[773] *Id.* at 5.
[774] *Id.*
[775] Marcus R. Munafó & George Davey Smith, *Robust research needs many lines of evidence*, Nature (Jan. 23, 2018), https://www.nature.com/articles/d41586-018-01023-3#ref-CR3.
[776] *Id.*
[777] *Id.*
[778] *Id.*

II. John P.A. Ioannidis, *Why Most Published Research is False*, 2 PLoS Medicine 0696 (2005)

The article suggests"the high rate of nonreplication (lack of confirmation) of research discoveries is a consequence of the convenient, yet ill-founded strategy of claiming conclusive research findings solely on the basis of a single study assessed by formal statistical significance, typically for a *p*-value less than 0.05."[779] It looks at a number of different contributors to false positive findings and discusses solutions to this problem. Importantly, it stresses the need to focus on large studies, consider the totality of the evidence, and improve understanding of pre-study odds.[780] These solutions each involve considering more evidence and more scientific studies to contextualize any one given study. Nowhere does the article suggests requiring underlying data be made public or fewer studies be considered. EPA's proposal contrarily emphasizes data disclosure above all other practices for ensuring scientific integrity—and will result in fewer studies being considered to shed light on the scientific truth.

The author of this article has specifically criticized EPA's Proposal, saying that, if it is finalized, "science will be practically eliminated from all decision-making processes" and "[r]egulation would then depend uniquely on opinion and whim."[781] The author highlights the inherent problem in EPA's Proposal, that "most of the raw data from past studies are not publicly available" and that indeed "[i]n a random sample of the biomedical literature (2000–2014) none of 268 papers shared all of their raw data. . . [and] [o]nly one shared a full research protocol."[782] EPA has not addressed this major issue that suggests the Proposal would bar EPA from relying on massive amounts of scientific research. The article notes that reproducibility issues vary across the disciplines and that in many areas in which EPA operates, a solid and large foundation of scientific research has produced credible and widely-affirmed findings, including "in fields such as air pollution and climate change."[783] Even in these other fields, however, it firmly states that "simply ignoring science that has not yet attained such standards, is a nightmare."[784]

III. Marcia McNutt, *Reproducibility*, 343 Science 229 (2014), http://science.sciencemag.org/content/343/6168/229.long

EPA cites an announcement by Science that, in response to reports "that a troubling proportion of peer-reviewed preclinical studies are not reproducible,"[785] Science is adopting new policies requiring authors making submissions to the journal to disclose "whether there was a pre-experimental plan for data handling (such as how to deal with outliers), whether they conducted a sample size estimation to ensure a sufficient signal-to-noise ratio, whether samples were treated randomly, and whether the experimenter was blind to the conduct of the

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[779] John P.A. Ioannidis, *Why Most Published Research is False*, 2 PLoS Medicine 0696 (2005).
[780] *Id.* at 0700-0701
[781] John P.A. Ioannidis, *All science should inform policy and regulation*, 15 PLOS Med 1, 2 (May 3, 2018), http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1002576.
[782] *Id.* at 1.
[783] *Id.* at 2.
[784] *Id.* at 2.
[785] Marcia McNutt, *Reproducibility*, 343 Science 229 (2014), http://science.sciencemag.org/content/343/6168/229.long.

experiment."[786] While the article considers steps to increase reproducibility of science, it notes that data availability is not a necessary or sufficient step to ensure credibility of research findings, and that "ultimate responsibility lies with authors to be completely open with their methods, all of their findings, and the possible pitfalls that could invalidate their conclusions."[787] EPA's Proposal ignores the ability to assess studies through these other important indicators to assure their validity.

VI. *How Science Goes Wrong*, Economist (Oct. 21, 2013), https://www.economist.com/news/leaders/21588069-scientific-research-has-changed-world-now-it-needs-change-itself-how-science-goes-wrong

This article opposes the view that verification of a study depends solely on the underlying data being made publicly available. While it identifies that much scientific research is unable to be replicated, the solution it proposes include tightening standards, particularly in statistics, registering research protocols in advance and monitoring them, and: "[w]here possible, trial data also should be open for other researchers to inspect and test."[788] Thus, even to the extent it discusses data availability, it suggests data should be open for other *researchers*, as opposed to the public, and recognizes this may not always be possible.[789]

VII. Steve N. Goodman, *What does research reproducibility mean?*, 8 Science Translational Medicine 1 (2016), http://stm.sciencemag.org/content/8/341/341ps12.full

Rather than saying anything about agencies relying only on scientific studies where underlying data is made public, this article discusses the importance of clearly defining key terms in the discussion about scientific reproducibility, noting that there is a lack of standardized definitions of terms such as "reproducibility, replicability, reliability, robustness, and generalizability."[790] This raises a key issue of vagueness in EPA's proposal—EPA does not provide definition for key terms such as "independently validate" or "reproducible" and confusing mentions a "replication crisis" while citing to articles that speak to a "reproducibility crisis."

While providing definitions for these various terms, the article notes that there terms all represent various methods of attempting to verify studies to ensure "scientific claims based on scientific results are true" and cautions against "treating reproducibility as an end in itself—rather than as an imperfect surrogate for scientific truth."[791] Instead, it promoted the view of looking across studies to "assess their cumulative evidential weight."[792] EPA Proposal thus directly contradicts the suggestions of this article.

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[786] *Id.*
[787] *Id.*
[788] *How Science Goes Wrong*, Economist (Oct. 21, 2013), https://www.economist.com/news/leaders/21588069-scientific-research-has-changed-world-now-it-needs-change-itself-how-science-goes-wrong.
[789] *Id.*
[790] Steve N. Goodman, *What does research reproducibility mean?*, 8 Science Translational Medicine 1 (2016), http://stm.sciencemag.org/content/8/341/341ps12.full.
[791] *Id.*
[792] *Id.* at 3.

Footnote 13: EPA has not consistently followed previous EPA policy (e.g, EPA's Scientific Integrity Guidance, referenced above) that encouraged the use of non-proprietary data and models.

While EPA in a footnotes suggests that EPA has not consistently followed EPA's EPA's Scientific Integrity Policy encouraging the use of non-proprietary data and models, it misses the fact that EPA's policy was not written as an absolute standard, but was intended to be a flexible one. The policy states only that "the use of non-proprietary data and models are encouraged, when feasible, to increase transparency."[793] EPA must thus explain and justify its deviation from its prior flexible approach that the Proposal now imposes.

Footnote 14: https://www.whitehouse.gov/wp-content/uploads/2017/11/2005-M-05-03-Issuance-of-OMBs-Final-Information-Quality-Bulletin-for-Peer-Review-December-16-2004.pdf

The Proposal appears to issue a requirement for independent peer review of all *pivotal regulatory science* used to justify *regulatory decisions,* consistent with the requirements of the OMB Final Information Quality Bulletin for Peer Review. EPA cites to OMB's Final Information Quality Bulletin for Peer Review, explaining existing peer review requirements that nowhere does EPA suggest are not already being complied with.

As discussed in our comments, there is some vagueness as to whether the Proposal maintains, expands, or narrows these already existing requirements. OMB's bulletin underwent a rigorous stakeholder process including response to comments on multiple drafts from stakeholders, a federal agency workshop at NAS, outreach to major scientific organizations and societies, a formal interagency review.[794] EPA's Proposal has not gone through nearly the same level of review, or as our comments detail, even met the minimum legal requirements for consultation and review. OMB's guidance further provides that agencies should consider the "tradeoffs between depth of peer review and timeliness"[795] This includes considering a benefit-cost framework for peer review that takes into account "the direct costs of the peer review activity and those stemming from potential delay in government and private actions that can result from peer review."[796] As our comments detail, EPA has not provided any meaningful benefit-cost analysis of the Proposal. Thus, it would be improper and in conflict with OMB's guidance for EPA to be expanding the peer review requirements through this Proposal.

Footnote 15: February 22, 2002 (67 FR 8453) OMB's Guidelines Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information (2002)

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[793] EPA, *Scientific Integrity Policy* at 4.
[794] *Final Information Quality Bulletin for Peer Review*, 70 Fed. Reg. 2664 (Jan. 14, 2005).
[795] *Id.* at 2,668.
[796] *Id.* at 2,668